

US3672388 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:17:10

All time stamps listed in this document are displayed in GMT

US3672388

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Participant ID

US3672388

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

US3672388

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 31 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 |

US3672388

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date of Birth (MMM yyyy) | (b) (6) 1949 |
| Age | 70 |
| Age Units | YEARS |
| Age (Derived) | 70 |
| 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 |

US3672388

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------------------|----------------------------------------------|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 31 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 type="radio"/> |
| | Amendment 3 <input checked="" type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | POSTMENOPAUSAL |
| Start date (dd MMM yyyy) | UN JUN 1995 |
| 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) | JUN 1995 |
| Start Year (derived) | 1995 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3672388

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | CHRONIC CONSTIPATION |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2001 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | JAN 2001 |
| Stop Year (derived) | 2001 |

US3672388

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | COLECTOMY |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2001 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | JAN 2001 |
| Stop Year (derived) | 2001 |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | HISTORY OF MULTIPLE SMALL BOWEL OBSTRUCTIONS |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | LOWER EXTREMITY EDEMA |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------------|------------------------------------------------------------------|
| Condition | DERMAL FILLER INJECTIONS |
| Start date (dd MMM yyyy) | UN UNK 2011 |
| 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 2011 |
| Start Year (derived) | 2011 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 21:51:10

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------|------------------------------------------------------------------|
| Condition | COSMETIC BOTOX INJECTIONS |
| Start date (dd MMM yyyy) | UN UNK 2011 |
| 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 2011 |
| Start Year (derived) | 2011 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3672388

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 31 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:38 (24 HR) |
| Vital Signs Date and Time (derived) | 31 AUG 2020 12:38 |
| Height (xxx.x) | 155.8 cm |
| Weight (xxx.x) | 45.3 kg |
| BMI (xxx.x) | 18.66222 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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 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) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*) 31 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 JUN 1995

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| 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 | True |
| Specify | RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 31 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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 189173

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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|--------|---------------|
| 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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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) | 31 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:38 (24 HR) |
| Vital Signs Date and Time (derived) | 31 AUG 2020 12:38 |
| Temperature (xxx.x) | 98.0 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 81 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 76 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|
| 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) | 31 AUG 2020 |
| Time of assessment (00:00-23:59) | 13:45 (24 HR) |
| Vital Signs Date and Time (derived) | 31 AUG 2020 13:45 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 65 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 114 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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 13:15 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 13:15

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) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

13:03 (24 HR)

Collection date and time (derived)

31 AUG 2020 13:03

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 31 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 12:29 | 31 AUG 2020 12:29 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

31 AUG 2020 13:49

PC Open Date & Time

31 AUG 2020 13:35

PC Close Date & Time

31 AUG 2020 16:05

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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 97.6 °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 | 31 AUG 2020 20:38 |
| PC Open Date & Time | 31 AUG 2020 17:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

97.6 °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

01 SEP 2020 14:18

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 21:18

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

97.5 °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

04 SEP 2020 22:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 17:22

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 08:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

31 AUG 2020 13:50

PC Open Date & Time

31 AUG 2020 13:35

PC Close Date & Time

31 AUG 2020 16:05

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

31 AUG 2020 20:39

PC Open Date & Time

31 AUG 2020 17:00

PC Close Date & Time

01 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

01 SEP 2020 14:19

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

02 SEP 2020 21:19

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

03 SEP 2020 16:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

04 SEP 2020 22:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

05 SEP 2020 17:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 08:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 31 AUG 2020 13:51 |
| PC Open Date & Time | 31 AUG 2020 13:35 |
| PC Close Date & Time | 31 AUG 2020 16:05 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 31 AUG 2020 20:39 |
| PC Open Date & Time | 31 AUG 2020 17:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

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)

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 01 SEP 2020 14:19 |
| PC Open Date & Time | 01 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

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 ☒

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 21:19 |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

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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US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 SEP 2020 16:38 |
| PC Open Date & Time | 03 SEP 2020 12:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

56 of 1979

EAB) (1725)

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 SEP 2020 22:36 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

58 of 1979

EAB) (1725)

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 17:23 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

60 of 1979

EAB) (1725)

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 08:05 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3672388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------|-------------------------------------------|
| 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) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:47 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 11:47 |
| Temperature (xxx.x) | 98.0 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) | 13 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 68 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------|-----------------------------------------------|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:56 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 12:56 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 123 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 67 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

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) 28 SEP 2020

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

Treatment Date and Time (derived) 28 SEP 2020 12:23

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

What was the frequency of the study treatment dosing? ONCE

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

US3672388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

12:04 (24 HR)

Collection date and time (derived)

28 SEP 2020 12:04

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 28 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:55 | 28 SEP 2020 11:55 |
| Nasopharyngeal Swab 2 | No | | |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

28 SEP 2020 12:58

PC Open Date & Time

28 SEP 2020 12:43

PC Close Date & Time

28 SEP 2020 15:13

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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 96.6 °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 | 28 SEP 2020 18:42 |
| PC Open Date & Time | 28 SEP 2020 16:08 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 15:52

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

97.9 °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

30 SEP 2020 17:24

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

02 OCT 2020 09:22

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 10:06

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 19:57

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

04 OCT 2020 20:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

28 SEP 2020 12:59

PC Open Date & Time

28 SEP 2020 12:43

PC Close Date & Time

28 SEP 2020 15:13

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

28 SEP 2020 18:43

PC Open Date & Time

28 SEP 2020 16:08

PC Close Date & Time

29 SEP 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

29 SEP 2020 15:52

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

30 SEP 2020 17:24

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

02 OCT 2020 09:22

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

03 OCT 2020 10:06

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

03 OCT 2020 19:57

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 20:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 12:59 |
| PC Open Date & Time | 28 SEP 2020 12:43 |
| PC Close Date & Time | 28 SEP 2020 15:13 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 18:43 |
| PC Open Date & Time | 28 SEP 2020 16:08 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 1979

EAB) (1725)

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 SEP 2020 15:53 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

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 ☒

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 SEP 2020 17:25 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

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 ☒

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 OCT 2020 09:23 |
| PC Open Date & Time | 01 OCT 2020 12:00 |
| PC Close Date & Time | 02 OCT 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

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 ☒

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 OCT 2020 10:07 |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 OCT 2020 19:58 |
| PC Open Date & Time | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

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 ☒

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 04 OCT 2020 20:01 |
| PC Open Date & Time | 04 OCT 2020 12:00 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------------------------------------------------------------|------------------------------|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 05 OCT 2020 12:00 |
| PC Close Date & Time | 06 OCT 2020 11:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------------------------------------------------------------------|------------------------------|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 06 OCT 2020 12:00 |
| PC Close Date & Time | 07 OCT 2020 11:59 |

US3672388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:41

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------|-----------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 28 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 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 28 OCT 2020 |
| Time of assessment (00:00-23:59) | 10:56 (24 HR) |
| Vital Signs Date and Time (derived) | 28 OCT 2020 10:56 |
| 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) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

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.

US3672388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

11:22 (24 HR)

Collection date and time (derived)

28 OCT 2020 11:22

US3672388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:08:44

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| 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 | 03 NOV 2020 17:44:44 |
| Patient Cloud Open Date & Time | 31 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 04 NOV 2020 23:59 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 71 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 18:12:48

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 82 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 89 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 28 NOV 2020 08:52:42 |
| Patient Cloud Open Date & Time | 25 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 29 NOV 2020 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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 | 04 DEC 2020 12:03:33 |
| Patient Cloud Open Date & Time | 02 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 06 DEC 2020 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

09 DEC 2020 12:06:08

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 10:30:27

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

24 DEC 2020 08:49:12

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☒

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 DEC 2020 10:50:09

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

08 JAN 2021 12:42:01

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

15 JAN 2021 12:00:52

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 15:24:36

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 07:42:45

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 159 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 166 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 10 FEB 2021 08:59:35 |
| Patient Cloud Open Date & Time | 10 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 14 FEB 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

17 FEB 2021 13:45:49

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 14:16:31

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 10:41:55

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 194 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 13 MAR 2021 17:56:56 |
| Patient Cloud Open Date & Time | 10 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 14 MAR 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 13:02:28

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

24 MAR 2021 20:44:50

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

03 APR 2021 09:40:32

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 11:50:03

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 07:29:18

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| 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 | 21 APR 2021 17:02:54 |
| Patient Cloud Open Date & Time | 21 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 25 APR 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

30 APR 2021 12:16:07

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 306 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 11 JUL 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐
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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 25 AUG 2021 00:01 |
|----------------------------------------------------|-------------------|

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 29 AUG 2021 23:59 |
|-----------------------------------------------------|-------------------|

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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="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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 26 SEP 2021 23:59 |
|-----------------------------------------------------|-------------------|

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 10 OCT 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 17 OCT 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 24 OCT 2021 23:59 |
|-----------------------------------------------------|-------------------|

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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="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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐
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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| TIMEPOINT | DAY 453 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 01 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 05 DEC 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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="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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 15 DEC 2021 00:01 |
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|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 19 DEC 2021 23:59 |
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US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 26 DEC 2021 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐
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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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="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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
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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"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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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"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
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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"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 23 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 27 FEB 2022 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 20 APR 2022 00:01 |
|----------------------------------------------------|-------------------|

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 24 APR 2022 23:59 |
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US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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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"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
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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"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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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"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 17 JUL 2022 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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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"/> |
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| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 24 JUL 2022 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 31 JUL 2022 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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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"/> |
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 10 AUG 2022 00:01 |
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| Patient Cloud Close Date & Time | 14 AUG 2022 23:59 |
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US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 719

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

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

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

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

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

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

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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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 ☐ 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 ☐

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

| | |
|----------------------------------------------------|-------------------|
| Patient Cloud Open Date & Time | 05 OCT 2022 00:01 |
|----------------------------------------------------|-------------------|

| | |
|-----------------------------------------------------|-------------------|
| Patient Cloud Close Date & Time | 09 OCT 2022 23:59 |
|-----------------------------------------------------|-------------------|

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| | |
|-----------------------------------------------------|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 19 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 23 OCT 2022 23:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

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

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

| 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="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"/> |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3672388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:17:10

| 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 |
|-------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Yes | No | 01 MAR 2021 16:17:04 |

US3672388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 16 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 |
|------------|--------|

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3672388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

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.

US3672388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

11:22 (24 HR)

Collection date and time (derived)

16 MAR 2021 11:22

US3672388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 18:52:01

Generated On: 10 Jun 2021 09:17:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672388

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 18:52:01

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672388

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672388

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:17:10

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3672388

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 21 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 |
|------------|---------------|

US3672388

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

Date of updated informed consent (dd MMM yyyy) 21 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 21 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3672388

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

11:27 (24 HR)

Collection date and time (derived)

21 JAN 2021 11:27

US3672388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 21 JAN 2021 |
| Collection time (00:00 - 23:59) | 11:08 |
| Collection Date and Time (derived) | 21 JAN 2021 11:08 |

US3672388

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 21:51:09

Generated On: 10 Jun 2021 09:17:10

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | |
| Adverse event | GERD |
| 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) | UN SEP 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | UN OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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EAB) (1725)

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US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 21:51:09

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 21:51:09

Generated On: 10 Jun 2021 09:17:10

| | |
|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AEID | USA-US116-2021-MRNA-1273-P30 1000004 |
| Adverse event | RECURRENT SMALL BOWEL OBSTRUCTION |
| 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) | 01 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) | 04 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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) | 02 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 04 NOV 2020 |
| 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) 08 Apr 2021 21:51:09

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 21:51:09

Generated On: 10 Jun 2021 09:17:10

SUBJECT HAS MEDICAL
HISTORY OF MULTIPLE SMALL
BOWEL OBSTRUCTIONS.
SUBJECT WENT TO ER ON
11/01/20 COMPLAINING OF
ABDOMINAL PAIN, WAS SENT
HOME. 11/02/2020 WENT BACK
TO ED COMPLAINING OF
ABDOMINAL PAIN AND
NAUSEA - SHE RECEIVED A CT
SCAN AND WAS DIAGNOSED
WITH A SMALL BOWEL
OBSTRUCTION AND WAS
ADMITTED. SUBJECT
RECEIVED NASOGASTRIC TUBE
PROCEDURE AND WAS
DISCHARGED ON 11/04/20.

11/4/2020 LABS:

NA 134

CBC 16.1

MEAN CORPUSCULAR HGB 32.8

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

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

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

Yes ☒

No ☐

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

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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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US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | 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) | UN 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) | | UN 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"/> |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Name of Medication ISOVUE

Prophylaxis Yes ☐
No ☒

Indication RECURRENT SMALL BOWEL
OBSTRUCTION

Dose per administration 90

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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US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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 checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 02 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 02 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication RECURRENT SMALL BOWEL
OBSTRUCTION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

| | | |
|----------------------------------------------------|--------------------------|-------------------------------------|
| | 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 checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 03 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 03 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication DIFFICULTY SLEEPING

Dose per administration .25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 1979

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Name of Medication HCTZ/TRIAMTERENE

Prophylaxis Yes ☐
No ☒

Indication LOWER EXTREMITY EDEMA

Dose per administration 25/37.5

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

350 of 1979

EAB) (1725)

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

| | | |
|----------------------------------------------------|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2001 | |
| 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"/> |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 18:33:54

Generated On: 10 Jun 2021 09:17:10

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|-----------------------------------------|----------------------------|---------------|---------------------------------|
| 02 NOV 2020 | NASOGASTRIC TUBE | Adverse Event | |
| 01 NOV 2020 | CT SCAN (WITHOUT CONTRAST) | Adverse Event | |
| 02 NOV 2020 | CT SCAN (WITH CONTRAST) | Adverse Event | |

US3672388

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:17:10

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

US3672388

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:10

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 ☐

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

| | |
|----------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US116-2021-MRNA-1273-P301000004 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | CYNTHIA |
| Investigator's Last Name | STROUT |
| Site Address: Street | 1156 BOWMAN ROAD |
| Site Address: City | MOUNT PLEASANT |
| Site Address: State | |
| Site Address: Postal Code | 29464 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US116-2021-MRNA-1273-P301000004 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | CYNTHIA |
| Investigator's Last Name | STROUT |
| Site Address: Street | 1156 BOWMAN ROAD |
| Site Address: City | MOUNT PLEASANT |
| Site Address: State | |
| Site Address: Postal Code | 29464 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 22/JAN/2021 15:16 |
| 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 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US116-2021-MRNA-1273-P301000004 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | CYNTHIA |
| Investigator's Last Name | STROUT |
| Site Address: Street | 1156 BOWMAN ROAD |
| Site Address: City | MOUNT PLEASANT |
| Site Address: State | |
| Site Address: Postal Code | 29464 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 03/FEB/2021 11:54 |
| 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 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US116-2021-MRNA-1273-P301000004 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | CYNTHIA |
| Investigator's Last Name | STROUT |
| Site Address: Street | 1156 BOWMAN ROAD |
| Site Address: City | MOUNT PLEASANT |
| Site Address: State | |
| Site Address: Postal Code | 29464 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 16/FEB/2021 13:33 |
| 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 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US116-2021-MRNA-1273-P301000004 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | CYNTHIA |
| Investigator's Last Name | STROUT |
| Site Address: Street | 1156 BOWMAN ROAD |
| Site Address: City | MOUNT PLEASANT |
| Site Address: State | |
| Site Address: Postal Code | 29464 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 04/MAR/2021 08:36 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US116-2021-MRNA-1273-P301000004 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | CYNTHIA |
| Investigator's Last Name | STROUT |
| Site Address: Street | 1156 BOWMAN ROAD |
| Site Address: City | MOUNT PLEASANT |
| Site Address: State | |
| Site Address: Postal Code | 29464 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 19/MAR/2021 11:43 |
| 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 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 15:33:33

Generated On: 10 Jun 2021 09:17:10

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| SAEID | USA-US116-2021-MRNA-1273-P301000004 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | CYNTHIA |
| Investigator's Last Name | STROUT |
| Site Address: Street | 1156 BOWMAN ROAD |
| Site Address: City | MOUNT PLEASANT |
| Site Address: State | |
| Site Address: Postal Code | 29464 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 6 |
| Date of submission (Pre-filled from custom function) | 05/APR/2021 10:51 |
| 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

US3672388 (Prod: Coastal Carolina Research Center)

US3672388

Form: Participant Creation

Generated On: 10 Jun 2021 09:17:10

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'US3672388' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 16:34:55 |

US3672388

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 31 Aug 2020 17:03:04 |

US3672388

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 16:34:57 |

US3672388

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:03:04 |

US3672388

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'SCRN' | System | 31 Aug 2020 17:03:04 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered (b) (6) 1949' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 16:34:58 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '70' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'YEARS' | System | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '70' | System | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Female (F)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Ethnicity](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'I' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:10

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:03:41 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Aug 2020' | System | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2020' | System | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Amendment 3 (3)' | (b) (4), (b) (6) | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:03:56 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 16:34:57 |

US3672388

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:10

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'I' | System | 31 Aug 2020 17:03:59 |

US3672388

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 31 Aug 2020 17:03:59 |

US3672388

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:17:10

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 21 Oct 2020 20:05:41 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:05:15 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

[Condition](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Oct 2020 20:07:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Oct 2020 20:07:43 |
| Data point term sent to Coder | System | 21 Oct 2020 20:06:40 |
| User entered 'postmenopausal' | (b) (4), (b) (6) | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un Jun 1995' | (b) (4), (b) (6) | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jun 1995' | System | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '1995' | System | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 21 Oct 2020 20:06:16 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

[Condition](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation chronic - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:25:04 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:25:04 |
| Data point term sent to Coder | System | 22 Jan 2021 20:24:07 |
| User entered 'chronic constipation' | (b) (4), (b) (6) | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un UNK 2000' | (b) (4), (b) (6) | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un UNK 2001' | (b) (4), (b) (6) | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2000' | System | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2000' | System | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2001' | System | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2001' | System | 22 Jan 2021 20:23:15 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

[Condition](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colectomy, LLT: Colectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:25:03 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Jan 2021 20:25:03 |
| Data point term sent to Coder | System | 22 Jan 2021 20:24:07 |
| User entered 'colectomy' | (b) (4), (b) (6) | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un UNK 2001' | (b) (4), (b) (6) | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un UNK 2001' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2001' | System | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2001' | System | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2001' | System | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2001' | System | 22 Jan 2021 20:23:37 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

Condition

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 24 Jan 2021 12:04:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Jan 2021 12:04:47 |
| Data point term sent to Coder | System | 22 Jan 2021 20:25:08 |
| User entered 'history of multiple small bowel obstructions' | (b) (4), (b) (6) | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un UNK 2001' | (b) (4), (b) (6) | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2001' | System | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2001' | System | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 22 Jan 2021 20:24:36 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

Condition

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Difficulty sleeping - version MedDRA\\23.0. | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Feb 2021 14:46:47 |
| Data point term sent to Coder | (b) (4) | |
| User entered 'Difficulty sleeping' | System | 12 Feb 2021 14:45:59 |
| | (b) (4), (b) (6) | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un Nov 2019' | (b) (4), (b) (6) | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Nov 2019' | System | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2019' | System | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 12 Feb 2021 14:45:03 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

[Condition](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Feb 2021 14:46:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Feb 2021 14:46:47 |
| Data point term sent to Coder | System | 12 Feb 2021 14:45:59 |
| User entered 'lower extremity edema' | (b) (4), (b) (6) | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un UNK 2001' | (b) (4), (b) (6) | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:42 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2001' | System | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2001' | System | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 12 Feb 2021 14:45:37 |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Mar 2021 15:32:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Mar 2021 15:32:12 |
| Data point term sent to Coder | System | 30 Mar 2021 15:31:11 |
| User entered 'Dermal Filler Injections' | (b) (4), (b) (6) | 30 Mar 2021 15:30:30 |
| | | |
| | | |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered 'un UNK 2011' | (b) (4), (b) (6) | 30 Mar 2021 15:30:30 |
| | | |
| | | |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 15:30:30 |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Mar 2021 15:30:30 |
| | | |
| | | |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 15:30:30 |
| | | |
| | | |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 15:30:30 |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2011' | System | 30 Mar 2021 15:30:30 |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2011' | System | 30 Mar 2021 15:30:30 |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 30 Mar 2021 15:30:30 |

US3672388

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 30 Mar 2021 15:30:30 |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Mar 2021 15:33:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 30 Mar 2021 15:33:12 |
| Data point term sent to Coder | System | 30 Mar 2021 15:32:11 |
| User entered 'Cosmetic Botox Injections' | (b) (4), (b) (6) | 30 Mar 2021 15:31:23 |
| | | |
| | | |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered 'un UNK 2011' | (b) (4), (b) (6) | 30 Mar 2021 15:31:23 |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 15:31:23 |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Mar 2021 15:31:23 |
| | | |
| | | |

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Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered empty. | (b) (4), (b) (6) | 30 Mar 2021 15:31:23 |
| | | |
| | | |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:11:29 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User entered '0' | (b) (4), (b) (6) | 30 Mar 2021 15:31:23 |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'Jan 2011' | System | 30 Mar 2021 15:31:23 |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '2011' | System | 30 Mar 2021 15:31:23 |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 30 Mar 2021 15:31:23 |

US3672388

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 30 Mar 2021 15:31:23 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '12:38' | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '31 Aug 2020 12:38' | System | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '155.8' cm | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |
| DataPoint set to visible. | System | 31 Aug 2020 17:03:59 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '45.3' kg | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |
| DataPoint set to visible. | System | 31 Aug 2020 17:03:59 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '18.66222' | System | 31 Aug 2020 17:24:07 |
| DataPoint set to visible. | System | 31 Aug 2020 17:03:59 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'kg/m2' | System | 31 Aug 2020 17:24:07 |
| DataPoint set to visible. | System | 31 Aug 2020 17:03:59 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'bpm' | System | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'breaths/min' | System | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'mmHg' | System | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'mmHg' | System | 31 Aug 2020 17:24:07 |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| | | |

US3672388

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |

US3672388

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 31 Aug 2020 17:24:26 |

US3672388

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:24:26 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

If No, what is the reason?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 18:13:43 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 20:05:31 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 10 Oct 2020 00:00:59 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

[Date of surgery unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'un Jun 1995' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:17:10

Date of last menstruation unknown

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:24:53 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 31 Aug 2020 17:25:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 31 Aug 2020 17:25:41 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 31 Aug 2020 17:25:41 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 31 Aug 2020 17:25:35 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '0' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'I' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'I' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:10

[Specify](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'resident in a community with ongoing person to person transmission' | (b) (4), (b) (6) | 31 Aug 2020 17:25:35 |

US3672388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 31 Aug 2020 17:25:56 |

US3672388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:25:56 |

US3672388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:25:56 |

US3672388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'VISIT1' | System | 31 Aug 2020 17:25:56 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 16:54:43 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '189173' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 16:54:43 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------------|---------------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 31 Aug 2020 16:54:43 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:02 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:02 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:02 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:02 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:02 |

US3672388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 21 Oct 2020 19:59:26 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 08:44:57 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 08:44:56 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:10

Height

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:10

Weight

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:10

Height

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:10

Weight

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '12:38' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '31 Aug 2020 12:38' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '98.0' F | (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '81' | (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'bpm' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '14' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'breaths/min' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '111' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '76' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:10

Height

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:10

[Weight](#)

| Audit | User | Time (GMT) |
|------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered missing code ND - Not Done. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '13:45' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '31 Aug 2020 13:45' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '97.7' F | (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '65' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'bpm' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '14' | (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'breaths/min' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '114' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '75' | (b) (4), (b) (6) | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 31 Aug 2020 17:55:30 |

US3672388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:09 |

US3672388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:09 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '13:15' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '31 Aug 2020 13:15' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'ONCE' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'INTRAMUSCULAR' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:43 |

US3672388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:43 |

US3672388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '13:03' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:26:43 |

US3672388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '31 Aug 2020 13:03' | System | 31 Aug 2020 17:26:43 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:17:10

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '31 Aug 2020' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '12:29' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '31 Aug 2020 12:29' | System | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered empty. | System | 31 Aug 2020 17:27:45 |

US3672388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Aug 2020 17:27:49 |

US3672388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 31 Aug 2020 17:27:49 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:48:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd264cdda-be15-4cdc-98e6-8fd05ffcb854' User entered 'Yes (Y)' | System | 31 Aug 2020 17:55:17 |
| | System | 31 Aug 2020 17:55:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:49:16', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd264cdda-be15-4cdc-98e6-8fd05ffcb854' User entered '97.7' | System | 31 Aug 2020 17:55:17 |
| | System | 31 Aug 2020 17:55:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:49:33', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd264cdda-be15-4cdc-98e6-8fd05ffcb854' | System | 31 Aug 2020 17:55:17 |
| User entered 'No (N)' | System | 31 Aug 2020 17:55:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:49:40', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd264cdda-be15-4cdc-98e6-8fd05ffcb854' | System | 31 Aug 2020 17:55:17 |
| User entered '31 Aug 2020 13:49' | System | 31 Aug 2020 17:55:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 13:35' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 16:05' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:03', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '88e37c0e-d3b0-427a-acac-cc044d9c9a4b' User entered 'Yes (Y)' | System | 01 Sep 2020 00:39:23 |
| | System | 01 Sep 2020 00:39:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:08', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '88e37c0e-d3b0-427a-acac-cc044d9c9a4b' User entered '97.6' | System | 01 Sep 2020 00:39:23 |
| | System | 01 Sep 2020 00:39:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '88e37c0e-d3b0-427a-acac-cc044d9c9a4b' User entered 'No (N)' | System | 01 Sep 2020 00:39:23 |
| | System | 01 Sep 2020 00:39:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:19', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '88e37c0e-d3b0-427a-acac-cc044d9c9a4b' User entered '31 Aug 2020 20:38' | System | 01 Sep 2020 00:39:23 |
| | System | 01 Sep 2020 00:39:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 17:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 2' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:18:30', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '3c536b6b-c144-4f9a-9be2-e23543e97c12' User entered 'Yes (Y)' | System | 01 Sep 2020 18:18:52 |
| | System | 01 Sep 2020 18:18:52 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:18:39', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '3c536b6b-c144-4f9a-9be2-e23543e97c12' User entered '97.6' | System | 01 Sep 2020 18:18:52 |
| | System | 01 Sep 2020 18:18:52 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:18:43', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '3c536b6b-c144-4f9a-9be2-e23543e97c12' | System | 01 Sep 2020 18:18:52 |
| User entered 'No (N)' | System | 01 Sep 2020 18:18:52 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:18:50', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '3c536b6b-c144-4f9a-9be2-e23543e97c12' | System | 01 Sep 2020 18:18:52 |
| User entered '01 Sep 2020 14:18' | System | 01 Sep 2020 18:18:52 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 3' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:18:41', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a7a8559d-cd87-4ed8-9419-3b732d8234e0' User entered 'Yes (Y)' | System | 03 Sep 2020 01:19:00 |
| | System | 03 Sep 2020 01:19:00 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:18:47', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a7a8559d-cd87-4ed8-9419-3b732d8234e0' User entered '97.2' | System | 03 Sep 2020 01:19:00 |
| | System | 03 Sep 2020 01:19:00 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:18:52', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a7a8559d-cd87-4ed8-9419-3b732d8234e0' User entered 'No (N)' | System | 03 Sep 2020 01:19:00 |
| | System | 03 Sep 2020 01:19:00 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:18:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a7a8559d-cd87-4ed8-9419-3b732d8234e0' User entered '02 Sep 2020 21:18' | System | 03 Sep 2020 01:19:00 |
| | System | 03 Sep 2020 01:19:00 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 4' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:37:35', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e0d0b2bb-bdd2-41ee-b172-8902a3b8ff4f' User entered 'Yes (Y)' | System | 03 Sep 2020 20:37:50 |
| | System | 03 Sep 2020 20:37:50 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:37:40', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e0d0b2bb-bdd2-41ee-b172-8902a3b8ff4f' User entered '98.2' | System | 03 Sep 2020 20:37:50 |
| | System | 03 Sep 2020 20:37:50 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:37:45', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e0d0b2bb-bdd2-41ee-b172-8902a3b8ff4f' User entered 'No (N)' | System | 03 Sep 2020 20:37:50 |
| | System | 03 Sep 2020 20:37:50 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:37:48', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e0d0b2bb-bdd2-41ee-b172-8902a3b8ff4f' User entered '03 Sep 2020 16:37' | System | 03 Sep 2020 20:37:50 |
| | System | 03 Sep 2020 20:37:50 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 5' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:35:54', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '2dca1422-3a56-401e-98dc-edf32e4440b3' User entered 'Yes (Y)' | System | 05 Sep 2020 02:36:14 |
| | System | 05 Sep 2020 02:36:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:02', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '2dca1422-3a56-401e-98dc-edf32e4440b3' User entered '97.5' | System | 05 Sep 2020 02:36:14 |
| | System | 05 Sep 2020 02:36:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:07', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '2dca1422-3a56-401e-98dc-edf32e4440b3' | System | 05 Sep 2020 02:36:14 |
| User entered 'No (N)' | System | 05 Sep 2020 02:36:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '2dca1422-3a56-401e-98dc-edf32e4440b3' | System | 05 Sep 2020 02:36:14 |
| User entered '04 Sep 2020 22:36' | System | 05 Sep 2020 02:36:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 6' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:27', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '50d782c1-e223-4b1b-8c9d-257986eaf5db' User entered 'Yes (Y)' | System | 05 Sep 2020 21:22:46 |
| | System | 05 Sep 2020 21:22:46 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '50d782c1-e223-4b1b-8c9d-257986eaf5db' User entered '97.0' | System | 05 Sep 2020 21:22:46 |
| | System | 05 Sep 2020 21:22:46 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:40', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '50d782c1-e223-4b1b-8c9d-257986eaf5db' User entered 'No (N)' | System | 05 Sep 2020 21:22:46 |
| | System | 05 Sep 2020 21:22:46 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:43', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '50d782c1-e223-4b1b-8c9d-257986eaf5db' User entered '05 Sep 2020 17:22' | System | 05 Sep 2020 21:22:46 |
| | System | 05 Sep 2020 21:22:46 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 7' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:30', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'c00d6e95-e169-41cb-84e6-323593d12adb' User entered 'Yes (Y)' | System | 07 Sep 2020 12:04:53 |
| | System | 07 Sep 2020 12:04:53 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'c00d6e95-e169-41cb-84e6-323593d12adb' User entered '97.0' | System | 07 Sep 2020 12:04:53 |
| | System | 07 Sep 2020 12:04:53 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:40', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'c00d6e95-e169-41cb-84e6-323593d12adb' User entered 'No (N)' | System | 07 Sep 2020 12:04:53 |
| | System | 07 Sep 2020 12:04:53 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:44', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'c00d6e95-e169-41cb-84e6-323593d12adb' User entered '07 Sep 2020 08:04' | System | 07 Sep 2020 12:04:53 |
| | System | 07 Sep 2020 12:04:53 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:11', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0c31b8c0-0624-4389-b74c-7f684cfab4e3' | System | 31 Aug 2020 17:55:23 |
| User entered 'None (1)' | System | 31 Aug 2020 17:55:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:18', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0c31b8c0-0624-4389-b74c-7f684cfab4e3' User entered 'No (N)' | System | 31 Aug 2020 17:55:23 |
| | System | 31 Aug 2020 17:55:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:22', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0c31b8c0-0624-4389-b74c-7f684cfab4e3' User entered 'No (N)' | System | 31 Aug 2020 17:55:23 |
| | System | 31 Aug 2020 17:55:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:26', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0c31b8c0-0624-4389-b74c-7f684cfab4e3' | System | 31 Aug 2020 17:55:23 |
| User entered 'None (1)' | System | 31 Aug 2020 17:55:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0c31b8c0-0624-4389-b74c-7f684cfab4e3' User entered '31 Aug 2020 13:50' | System | 31 Aug 2020 17:55:23 |
| | System | 31 Aug 2020 17:55:23 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 13:35' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 16:05' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:38', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8acbb3eb-fd3b-4921-8497-76f9f2bcabe1' User entered 'None (1)' | System | 01 Sep 2020 00:39:07 |
| | System | 01 Sep 2020 00:39:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:50', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8acbb3eb-fd3b-4921-8497-76f9f2bcabe1' User entered 'No (N)' | System | 01 Sep 2020 00:39:07 |
| | System | 01 Sep 2020 00:39:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:52', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8acbb3eb-fd3b-4921-8497-76f9f2bcabe1' User entered 'No (N)' | System | 01 Sep 2020 00:39:07 |
| | System | 01 Sep 2020 00:39:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:38:58', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8acbb3eb-fd3b-4921-8497-76f9f2bcabe1' User entered 'None (1)' | System | 01 Sep 2020 00:39:07 |
| | System | 01 Sep 2020 00:39:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:04', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8acbb3eb-fd3b-4921-8497-76f9f2bcabe1' User entered '31 Aug 2020 20:39' | System | 01 Sep 2020 00:39:07 |
| | System | 01 Sep 2020 00:39:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 17:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 2' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:18:58', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6962dd34-2f10-4dcb-91bf-97e486dd9e66' | System | 01 Sep 2020 18:19:20 |
| User entered 'None (1)' | System | 01 Sep 2020 18:19:20 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:02', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6962dd34-2f10-4dcb-91bf-97e486dd9e66' User entered 'No (N)' | System | 01 Sep 2020 18:19:20 |
| | System | 01 Sep 2020 18:19:20 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:06', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6962dd34-2f10-4dcb-91bf-97e486dd9e66' | System | 01 Sep 2020 18:19:20 |
| User entered 'No (N)' | System | 01 Sep 2020 18:19:20 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6962dd34-2f10-4dcb-91bf-97e486dd9e66' | System | 01 Sep 2020 18:19:20 |
| User entered 'None (1)' | System | 01 Sep 2020 18:19:20 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:16', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6962dd34-2f10-4dcb-91bf-97e486dd9e66' | System | 01 Sep 2020 18:19:20 |
| User entered '01 Sep 2020 14:19' | System | 01 Sep 2020 18:19:20 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 3' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:01', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd8bc1d6c-afaa-4485-9f60-5354582442bd' User entered 'None (1)' | System | 03 Sep 2020 01:19:17 |
| | System | 03 Sep 2020 01:19:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:04', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd8bc1d6c-afaa-4485-9f60-5354582442bd' User entered 'No (N)' | System | 03 Sep 2020 01:19:17 |
| | System | 03 Sep 2020 01:19:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:07', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd8bc1d6c-afaa-4485-9f60-5354582442bd' User entered 'No (N)' | System | 03 Sep 2020 01:19:17 |
| | System | 03 Sep 2020 01:19:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:11', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd8bc1d6c-afaa-4485-9f60-5354582442bd' User entered 'None (1)' | System | 03 Sep 2020 01:19:17 |
| | System | 03 Sep 2020 01:19:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:14', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd8bc1d6c-afaa-4485-9f60-5354582442bd' User entered '02 Sep 2020 21:19' | System | 03 Sep 2020 01:19:17 |
| | System | 03 Sep 2020 01:19:17 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 4' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:37:55', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8a3f8dc2-768d-422e-9ebf-be14bee9b729' | System | 03 Sep 2020 20:38:14 |
| User entered 'None (1)' | System | 03 Sep 2020 20:38:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:37:58', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8a3f8dc2-768d-422e-9ebf-be14bee9b729' | System | 03 Sep 2020 20:38:14 |
| User entered 'No (N)' | System | 03 Sep 2020 20:38:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:02', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8a3f8dc2-768d-422e-9ebf-be14bee9b729' | System | 03 Sep 2020 20:38:14 |
| User entered 'No (N)' | System | 03 Sep 2020 20:38:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:08', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8a3f8dc2-768d-422e-9ebf-be14bee9b729' | System | 03 Sep 2020 20:38:14 |
| User entered 'None (1)' | System | 03 Sep 2020 20:38:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:11', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8a3f8dc2-768d-422e-9ebf-be14bee9b729' User entered '03 Sep 2020 16:38' | System | 03 Sep 2020 20:38:14 |
| | System | 03 Sep 2020 20:38:14 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 5' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:18', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '375616c8-04ef-4161-a736-34d6c3682845' | System | 05 Sep 2020 02:36:35 |
| User entered 'None (1)' | System | 05 Sep 2020 02:36:35 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:21', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '375616c8-04ef-4161-a736-34d6c3682845' User entered 'No (N)' | System | 05 Sep 2020 02:36:35 |
| | System | 05 Sep 2020 02:36:35 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:24', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '375616c8-04ef-4161-a736-34d6c3682845' User entered 'No (N)' | System | 05 Sep 2020 02:36:35 |
| | System | 05 Sep 2020 02:36:35 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '375616c8-04ef-4161-a736-34d6c3682845' | System | 05 Sep 2020 02:36:35 |
| User entered 'None (1)' | System | 05 Sep 2020 02:36:35 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '375616c8-04ef-4161-a736-34d6c3682845' | System | 05 Sep 2020 02:36:35 |
| User entered '04 Sep 2020 22:36' | System | 05 Sep 2020 02:36:35 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 6' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f06a79f2-e329-4efb-961d-f5c6a1e8f1f4' | System | 05 Sep 2020 21:23:07 |
| User entered 'None (1)' | System | 05 Sep 2020 21:23:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:53', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f06a79f2-e329-4efb-961d-f5c6a1e8f1f4' | System | 05 Sep 2020 21:23:07 |
| User entered 'No (N)' | System | 05 Sep 2020 21:23:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f06a79f2-e329-4efb-961d-f5c6a1e8f1f4' | System | 05 Sep 2020 21:23:07 |
| User entered 'No (N)' | System | 05 Sep 2020 21:23:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:22:59', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f06a79f2-e329-4efb-961d-f5c6a1e8f1f4' | System | 05 Sep 2020 21:23:07 |
| User entered 'None (1)' | System | 05 Sep 2020 21:23:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:02', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f06a79f2-e329-4efb-961d-f5c6a1e8f1f4' | System | 05 Sep 2020 21:23:07 |
| User entered '05 Sep 2020 17:23' | System | 05 Sep 2020 21:23:07 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 7' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:48', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'be74300e-65dd-4690-ba91-9de6976f1eed' | System | 07 Sep 2020 12:05:04 |
| User entered 'None (1)' | System | 07 Sep 2020 12:05:04 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'be74300e-65dd-4690-ba91-9de6976f1eed' User entered 'No (N)' | System | 07 Sep 2020 12:05:04 |
| | System | 07 Sep 2020 12:05:04 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:54', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'be74300e-65dd-4690-ba91-9de6976f1eed' | System | 07 Sep 2020 12:05:04 |
| User entered 'No (N)' | System | 07 Sep 2020 12:05:04 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'be74300e-65dd-4690-ba91-9de6976f1eed' | System | 07 Sep 2020 12:05:04 |
| User entered 'None (1)' | System | 07 Sep 2020 12:05:04 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:04:59', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'be74300e-65dd-4690-ba91-9de6976f1eed' User entered '07 Sep 2020 08:04' | System | 07 Sep 2020 12:05:04 |
| | System | 07 Sep 2020 12:05:04 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:40', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' User entered 'None (0)' | System | 31 Aug 2020 17:55:40 |
| | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:42', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' User entered 'None (0)' | System | 31 Aug 2020 17:55:40 |
| | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:45', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' User entered 'None (0)' | System | 31 Aug 2020 17:55:40 |
| | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:48', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' User entered 'None (0)' | System | 31 Aug 2020 17:55:40 |
| | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' User entered 'None (0)' | System | 31 Aug 2020 17:55:40 |
| | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:50:53', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' User entered 'None (0)' | System | 31 Aug 2020 17:55:40 |
| | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:51:10', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' | System | 31 Aug 2020 17:55:40 |
| User entered 'No (N)' | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T13:51:13', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '06e93d35-d2a7-4064-80e9-2044cd95b1c4' | System | 31 Aug 2020 17:55:40 |
| User entered '31 Aug 2020 13:51' | System | 31 Aug 2020 17:55:40 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 13:35' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 16:05' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 1, after vaccination (at home)' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:11', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered 'None (0)' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:14', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered 'None (0)' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:18', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered 'None (0)' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:20', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered 'None (0)' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered 'None (0)' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:26', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered 'None (0)' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered 'No (N)' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-08-31T20:39:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6214d776-d928-41fe-81c2-f529c1395cc1' User entered '31 Aug 2020 20:39' | System | 01 Sep 2020 00:39:38 |
| | System | 01 Sep 2020 00:39:38 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '31 Aug 2020 17:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 2' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:21', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' User entered 'None (0)' | System | 01 Sep 2020 18:19:44 |
| | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' User entered 'None (0)' | System | 01 Sep 2020 18:19:44 |
| | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:26', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' User entered 'None (0)' | System | 01 Sep 2020 18:19:44 |
| | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:29', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' User entered 'None (0)' | System | 01 Sep 2020 18:19:44 |
| | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:32', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' User entered 'None (0)' | System | 01 Sep 2020 18:19:44 |
| | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:35', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' User entered 'None (0)' | System | 01 Sep 2020 18:19:44 |
| | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:38', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' | System | 01 Sep 2020 18:19:44 |
| User entered 'No (N)' | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-01T14:19:42', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f0fc24e9-2b79-4e02-aea8-0a43eb7850e8' | System | 01 Sep 2020 18:19:44 |
| User entered '01 Sep 2020 14:19' | System | 01 Sep 2020 18:19:44 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 3' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:19', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered 'None (0)' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:22', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered 'None (0)' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:24', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered 'None (0)' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:27', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered 'None (0)' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered 'None (0)' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:34', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered 'None (0)' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered 'No (N)' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-02T21:19:41', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4fe6aa3b-f198-49e1-8ddb-8f1bbf4605a5' User entered '02 Sep 2020 21:19' | System | 03 Sep 2020 01:19:45 |
| | System | 03 Sep 2020 01:19:45 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 4' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' | System | 03 Sep 2020 20:38:47 |
| User entered 'None (0)' | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:27', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' | System | 03 Sep 2020 20:38:47 |
| User entered 'None (0)' | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:30', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' User entered 'None (0)' | System | 03 Sep 2020 20:38:47 |
| | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:33', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' User entered 'None (0)' | System | 03 Sep 2020 20:38:47 |
| | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' User entered 'None (0)' | System | 03 Sep 2020 20:38:47 |
| | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:39', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' User entered 'None (0)' | System | 03 Sep 2020 20:38:47 |
| | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:42', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' | System | 03 Sep 2020 20:38:47 |
| User entered 'No (N)' | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-03T16:38:45', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6845a68d-8851-4b58-b63d-34695ed36e92' | System | 03 Sep 2020 20:38:47 |
| User entered '03 Sep 2020 16:38' | System | 03 Sep 2020 20:38:47 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 5' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered 'None (0)' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:39', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered 'None (0)' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:42', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered 'None (0)' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:45', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered 'None (0)' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:48', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered 'None (0)' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered 'None (0)' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:54', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered 'No (N)' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-04T22:36:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '53e1d628-54e7-4a6b-b40c-8caa8b1a5a17' User entered '04 Sep 2020 22:36' | System | 05 Sep 2020 02:36:59 |
| | System | 05 Sep 2020 02:36:59 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 6' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:07', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' User entered 'None (0)' | System | 05 Sep 2020 21:23:29 |
| | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:10', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' User entered 'None (0)' | System | 05 Sep 2020 21:23:29 |
| | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:14', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' User entered 'None (0)' | System | 05 Sep 2020 21:23:29 |
| | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:16', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' User entered 'None (0)' | System | 05 Sep 2020 21:23:29 |
| | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:19', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' User entered 'None (0)' | System | 05 Sep 2020 21:23:29 |
| | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:21', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' User entered 'None (0)' | System | 05 Sep 2020 21:23:29 |
| | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' | System | 05 Sep 2020 21:23:29 |
| User entered 'No (N)' | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-05T17:23:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a9cdcfb0-99b2-4f07-9a7c-c23514dbaa66' User entered '05 Sep 2020 17:23' | System | 05 Sep 2020 21:23:29 |
| | System | 05 Sep 2020 21:23:29 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 7' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:10', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered 'None (0)' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:14', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered 'None (0)' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:15', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered 'None (0)' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:17', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered 'None (0)' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:19', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered 'None (0)' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:21', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered 'None (0)' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:24', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered 'No (N)' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-07T08:05:27', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'dc4d80ae-36ac-4e41-a436-fe8b586aa4f7' User entered '07 Sep 2020 08:05' | System | 07 Sep 2020 12:05:30 |
| | System | 07 Sep 2020 12:05:30 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Sep 2020 12:00' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '07 Sep 2020 11:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 17:56:29 |

US3672388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '10 Sep 2020' | (b) (4), (b) (6) | 14 Sep 2020 17:56:29 |

US3672388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Sep 2020 17:56:29 |

US3672388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 14 Sep 2020 17:56:29 |

US3672388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 17:56:37 |

US3672388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 14 Sep 2020 17:56:37 |

US3672388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 17:56:54 |

US3672388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '14 Sep 2020' | (b) (4), (b) (6) | 14 Sep 2020 17:56:54 |

US3672388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 14 Sep 2020 17:56:54 |

US3672388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 14 Sep 2020 17:56:54 |

US3672388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 14 Sep 2020 17:56:58 |

US3672388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 14 Sep 2020 17:56:58 |

US3672388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Sep 2020 17:25:04 |

US3672388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '21 Sep 2020' | (b) (4) (b) (4), (b) (6) | 21 Sep 2020 17:25:04 |

US3672388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 21 Sep 2020 17:25:04 |

US3672388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Sep 2020 17:25:04 |

US3672388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Sep 2020 17:25:07 |

US3672388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 21 Sep 2020 17:25:07 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Sep 2020 16:14:54 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 16:14:54 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 16:14:54 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'VISIT2' | System | 28 Sep 2020 16:14:54 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Timepoint](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '11:47' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '28 Sep 2020 11:47' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '98.0' F | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '74' | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'bpm' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '13' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'breaths/min' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '118' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '68' | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Timepoint](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '12:56' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '28 Sep 2020 12:56' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '98.5' F | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '76' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'bpm' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '14' | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'breaths/min' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '123' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '67' | (b) (4), (b) (6) | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 28 Sep 2020 17:17:02 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 16:15:06 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 16:15:06 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '12:23' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '28 Sep 2020 12:23' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). | (b) (4) (b) (4), (b) (6) | 29 Sep 2020 06:27:56 |
| Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'correct as entered. PD noted' (Site from System). | (b) (4), (b) (6) | 28 Sep 2020 17:08:52 |
| User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System). | System | 28 Sep 2020 16:52:39 |
| User entered 'Right Arm (RIGHT ARM)' | (b) (4), (b) (6) | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'ONCE' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:10

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'INTRAMUSCULAR' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:09:22 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:09:22 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '12:04' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:09:22 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '28 Sep 2020 12:04' | System | 28 Sep 2020 17:09:22 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:17:10

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '11:55' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '28 Sep 2020 11:55' | System | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

[Lab Test](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4), (b) (6) | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered empty. | System | 28 Sep 2020 17:13:48 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Sep 2020 17:14:13 |

US3672388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '1' | System | 28 Sep 2020 17:14:13 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:58:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0be1efb7-778b-4633-9e0e-9728ba4d6b64' User entered 'Yes (Y)' | System | 28 Sep 2020 16:58:49 |
| | System | 28 Sep 2020 16:58:49 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:58:34', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0be1efb7-778b-4633-9e0e-9728ba4d6b64' User entered '98.5' | System | 28 Sep 2020 16:58:49 |
| | System | 28 Sep 2020 16:58:49 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:58:39', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0be1efb7-778b-4633-9e0e-9728ba4d6b64' User entered 'No (N)' | System | 28 Sep 2020 16:58:49 |
| | System | 28 Sep 2020 16:58:49 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:58:45', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0be1efb7-778b-4633-9e0e-9728ba4d6b64' User entered '28 Sep 2020 12:58' | System | 28 Sep 2020 16:58:49 |
| | System | 28 Sep 2020 16:58:49 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 12:43' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 15:13' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'b802ea85-27be-48a7-a7f1-6542a7684222' | System | 28 Sep 2020 22:42:43 |
| User entered 'Yes (Y)' | System | 28 Sep 2020 22:42:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:34', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'b802ea85-27be-48a7-a7f1-6542a7684222' | System | 28 Sep 2020 22:42:43 |
| User entered '96.6' | System | 28 Sep 2020 22:42:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:38', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'b802ea85-27be-48a7-a7f1-6542a7684222' | System | 28 Sep 2020 22:42:43 |
| User entered 'No (N)' | System | 28 Sep 2020 22:42:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:41', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'b802ea85-27be-48a7-a7f1-6542a7684222' | System | 28 Sep 2020 22:42:43 |
| User entered '28 Sep 2020 18:42' | System | 28 Sep 2020 22:42:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 16:08' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 2' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:21', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '806f2fc6-cb10-4f00-a29e-7badef69e651' User entered 'Yes (Y)' | System | 29 Sep 2020 19:52:40 |
| | System | 29 Sep 2020 19:52:40 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '806f2fc6-cb10-4f00-a29e-7badef69e651' User entered '99.1' | System | 29 Sep 2020 19:52:40 |
| | System | 29 Sep 2020 19:52:40 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:29', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '806f2fc6-cb10-4f00-a29e-7badef69e651' | System | 29 Sep 2020 19:52:40 |
| User entered 'No (N)' | System | 29 Sep 2020 19:52:40 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:32', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '806f2fc6-cb10-4f00-a29e-7badef69e651' User entered '29 Sep 2020 15:52' | System | 29 Sep 2020 19:52:40 |
| | System | 29 Sep 2020 19:52:40 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 3' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '004e0c97-b074-431b-8035-542ada61a605' | System | 30 Sep 2020 21:24:18 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 21:24:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:09', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '004e0c97-b074-431b-8035-542ada61a605' User entered '97.9' | System | 30 Sep 2020 21:24:18 |
| | System | 30 Sep 2020 21:24:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '004e0c97-b074-431b-8035-542ada61a605' | System | 30 Sep 2020 21:24:18 |
| User entered 'No (N)' | System | 30 Sep 2020 21:24:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:14', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '004e0c97-b074-431b-8035-542ada61a605' | System | 30 Sep 2020 21:24:18 |
| User entered '30 Sep 2020 17:24' | System | 30 Sep 2020 21:24:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 4' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4f1a454a-3dbb-4139-8191-b208bd19ac12' User entered 'Yes (Y)' | System | 02 Oct 2020 13:22:26 |
| | System | 02 Oct 2020 13:22:26 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:17', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4f1a454a-3dbb-4139-8191-b208bd19ac12' User entered '96.8' | System | 02 Oct 2020 13:22:26 |
| | System | 02 Oct 2020 13:22:26 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:20', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4f1a454a-3dbb-4139-8191-b208bd19ac12' | System | 02 Oct 2020 13:22:26 |
| User entered 'No (N)' | System | 02 Oct 2020 13:22:26 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '4f1a454a-3dbb-4139-8191-b208bd19ac12' User entered '02 Oct 2020 09:22' | System | 02 Oct 2020 13:22:26 |
| | System | 02 Oct 2020 13:22:26 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 5' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:05:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd58e23d6-8c7e-4e5d-a17c-4281ee808a77' | System | 03 Oct 2020 14:06:23 |
| User entered 'Yes (Y)' | System | 03 Oct 2020 14:06:23 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:13', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd58e23d6-8c7e-4e5d-a17c-4281ee808a77' | System | 03 Oct 2020 14:06:23 |
| User entered '96.4' | System | 03 Oct 2020 14:06:23 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:16', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd58e23d6-8c7e-4e5d-a17c-4281ee808a77' | System | 03 Oct 2020 14:06:23 |
| User entered 'No (N)' | System | 03 Oct 2020 14:06:23 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:21', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd58e23d6-8c7e-4e5d-a17c-4281ee808a77' | System | 03 Oct 2020 14:06:23 |
| User entered '03 Oct 2020 10:06' | System | 03 Oct 2020 14:06:23 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 6' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a0c95623-5465-46fa-9eff-70e95787b27d' User entered 'Yes (Y)' | System | 03 Oct 2020 23:57:43 |
| | System | 03 Oct 2020 23:57:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a0c95623-5465-46fa-9eff-70e95787b27d' User entered '96.7' | System | 03 Oct 2020 23:57:43 |
| | System | 03 Oct 2020 23:57:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:34', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a0c95623-5465-46fa-9eff-70e95787b27d' | System | 03 Oct 2020 23:57:43 |
| User entered 'No (N)' | System | 03 Oct 2020 23:57:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:38', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a0c95623-5465-46fa-9eff-70e95787b27d' User entered '03 Oct 2020 19:57' | System | 03 Oct 2020 23:57:43 |
| | System | 03 Oct 2020 23:57:43 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 7' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:00:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd03a62d7-d6c8-4a61-b448-2b65872c2793' | System | 05 Oct 2020 00:01:08 |
| User entered 'Yes (Y)' | System | 05 Oct 2020 00:01:08 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:00:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd03a62d7-d6c8-4a61-b448-2b65872c2793' | System | 05 Oct 2020 00:01:08 |
| User entered '96.8' | System | 05 Oct 2020 00:01:08 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:01', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd03a62d7-d6c8-4a61-b448-2b65872c2793' | System | 05 Oct 2020 00:01:08 |
| User entered 'No (N)' | System | 05 Oct 2020 00:01:08 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:04', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd03a62d7-d6c8-4a61-b448-2b65872c2793' | System | 05 Oct 2020 00:01:08 |
| User entered '04 Oct 2020 20:01' | System | 05 Oct 2020 00:01:08 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:58:57', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1a85291b-b919-4ffa-8560-1a2cac7eed2f' User entered 'None (1)' | System | 28 Sep 2020 16:59:14 |
| | System | 28 Sep 2020 16:59:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1a85291b-b919-4ffa-8560-1a2cac7eed2f' User entered 'No (N)' | System | 28 Sep 2020 16:59:14 |
| | System | 28 Sep 2020 16:59:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:03', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1a85291b-b919-4ffa-8560-1a2cac7eed2f' User entered 'No (N)' | System | 28 Sep 2020 16:59:14 |
| | System | 28 Sep 2020 16:59:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:08', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1a85291b-b919-4ffa-8560-1a2cac7eed2f' User entered 'None (1)' | System | 28 Sep 2020 16:59:14 |
| | System | 28 Sep 2020 16:59:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:11', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1a85291b-b919-4ffa-8560-1a2cac7eed2f' User entered '28 Sep 2020 12:59' | System | 28 Sep 2020 16:59:14 |
| | System | 28 Sep 2020 16:59:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 12:43' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 15:13' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:49', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e742fd58-1e9b-4cf2-9352-e3e003198622' | System | 28 Sep 2020 22:43:06 |
| User entered 'None (1)' | System | 28 Sep 2020 22:43:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:52', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e742fd58-1e9b-4cf2-9352-e3e003198622' | System | 28 Sep 2020 22:43:06 |
| User entered 'No (N)' | System | 28 Sep 2020 22:43:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:55', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e742fd58-1e9b-4cf2-9352-e3e003198622' | System | 28 Sep 2020 22:43:06 |
| User entered 'No (N)' | System | 28 Sep 2020 22:43:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:42:59', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e742fd58-1e9b-4cf2-9352-e3e003198622' | System | 28 Sep 2020 22:43:06 |
| User entered 'None (1)' | System | 28 Sep 2020 22:43:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:01', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e742fd58-1e9b-4cf2-9352-e3e003198622' User entered '28 Sep 2020 18:43' | System | 28 Sep 2020 22:43:06 |
| | System | 28 Sep 2020 22:43:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 16:08' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 2' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:41', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '85f70f41-332f-4ba3-b220-0733c8072b1b' | System | 29 Sep 2020 19:53:01 |
| User entered 'Does not interfere with activity (2)' | System | 29 Sep 2020 19:53:01 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:44', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '85f70f41-332f-4ba3-b220-0733c8072b1b' User entered 'No (N)' | System | 29 Sep 2020 19:53:01 |
| | System | 29 Sep 2020 19:53:01 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '85f70f41-332f-4ba3-b220-0733c8072b1b' User entered 'No (N)' | System | 29 Sep 2020 19:53:01 |
| | System | 29 Sep 2020 19:53:01 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '85f70f41-332f-4ba3-b220-0733c8072b1b' User entered 'None (1)' | System | 29 Sep 2020 19:53:01 |
| | System | 29 Sep 2020 19:53:01 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:52:59', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '85f70f41-332f-4ba3-b220-0733c8072b1b' User entered '29 Sep 2020 15:52' | System | 29 Sep 2020 19:53:01 |
| | System | 29 Sep 2020 19:53:01 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 3' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '32346d23-39b0-4a6b-93bf-eee80ba1023a' | System | 30 Sep 2020 21:24:48 |
| User entered 'Does not interfere with activity (2)' | System | 30 Sep 2020 21:24:48 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '32346d23-39b0-4a6b-93bf-eee80ba1023a' User entered 'No (N)' | System | 30 Sep 2020 21:24:48 |
| | System | 30 Sep 2020 21:24:48 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:39', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '32346d23-39b0-4a6b-93bf-eee80ba1023a' User entered 'No (N)' | System | 30 Sep 2020 21:24:48 |
| | System | 30 Sep 2020 21:24:48 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:43', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '32346d23-39b0-4a6b-93bf-eee80ba1023a' User entered 'None (1)' | System | 30 Sep 2020 21:24:48 |
| | System | 30 Sep 2020 21:24:48 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:45', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '32346d23-39b0-4a6b-93bf-eee80ba1023a' User entered '30 Sep 2020 17:24' | System | 30 Sep 2020 21:24:48 |
| | System | 30 Sep 2020 21:24:48 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 4' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:27', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '172d96b5-67a5-49b7-bc3b-858c560966a7' | System | 02 Oct 2020 13:22:39 |
| User entered 'None (1)' | System | 02 Oct 2020 13:22:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:30', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '172d96b5-67a5-49b7-bc3b-858c560966a7' | System | 02 Oct 2020 13:22:39 |
| User entered 'No (N)' | System | 02 Oct 2020 13:22:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:32', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '172d96b5-67a5-49b7-bc3b-858c560966a7' | System | 02 Oct 2020 13:22:39 |
| User entered 'No (N)' | System | 02 Oct 2020 13:22:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:35', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '172d96b5-67a5-49b7-bc3b-858c560966a7' | System | 02 Oct 2020 13:22:39 |
| User entered 'None (1)' | System | 02 Oct 2020 13:22:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:37', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '172d96b5-67a5-49b7-bc3b-858c560966a7' User entered '02 Oct 2020 09:22' | System | 02 Oct 2020 13:22:39 |
| | System | 02 Oct 2020 13:22:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 5' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8622b624-99ac-4973-a435-5f42aa7b614b' User entered 'None (1)' | System | 03 Oct 2020 14:06:50 |
| | System | 03 Oct 2020 14:06:50 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8622b624-99ac-4973-a435-5f42aa7b614b' User entered 'No (N)' | System | 03 Oct 2020 14:06:50 |
| | System | 03 Oct 2020 14:06:50 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8622b624-99ac-4973-a435-5f42aa7b614b' User entered 'No (N)' | System | 03 Oct 2020 14:06:50 |
| | System | 03 Oct 2020 14:06:50 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:44', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8622b624-99ac-4973-a435-5f42aa7b614b' User entered 'None (1)' | System | 03 Oct 2020 14:06:50 |
| | System | 03 Oct 2020 14:06:50 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:46', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8622b624-99ac-4973-a435-5f42aa7b614b' User entered '03 Oct 2020 10:06' | System | 03 Oct 2020 14:06:50 |
| | System | 03 Oct 2020 14:06:50 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 6' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:41', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '74f32d97-6dcd-4cb4-a093-1903389a8a48' | System | 03 Oct 2020 23:57:59 |
| User entered 'None (1)' | System | 03 Oct 2020 23:57:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:44', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '74f32d97-6dcd-4cb4-a093-1903389a8a48' User entered 'No (N)' | System | 03 Oct 2020 23:57:59 |
| | System | 03 Oct 2020 23:57:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:48', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '74f32d97-6dcd-4cb4-a093-1903389a8a48' User entered 'No (N)' | System | 03 Oct 2020 23:57:59 |
| | System | 03 Oct 2020 23:57:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '74f32d97-6dcd-4cb4-a093-1903389a8a48' User entered 'None (1)' | System | 03 Oct 2020 23:57:59 |
| | System | 03 Oct 2020 23:57:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:54', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '74f32d97-6dcd-4cb4-a093-1903389a8a48' User entered '03 Oct 2020 19:57' | System | 03 Oct 2020 23:57:59 |
| | System | 03 Oct 2020 23:57:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 7' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:08', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8d077e0f-7dd6-453a-9287-25e89620b44d' | System | 05 Oct 2020 00:01:30 |
| User entered 'None (1)' | System | 05 Oct 2020 00:01:30 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:14', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8d077e0f-7dd6-453a-9287-25e89620b44d' | System | 05 Oct 2020 00:01:30 |
| User entered 'No (N)' | System | 05 Oct 2020 00:01:30 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:17', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8d077e0f-7dd6-453a-9287-25e89620b44d' | System | 05 Oct 2020 00:01:30 |
| User entered 'No (N)' | System | 05 Oct 2020 00:01:30 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

Please select one response below

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:22', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8d077e0f-7dd6-453a-9287-25e89620b44d' | System | 05 Oct 2020 00:01:30 |
| User entered 'None (1)' | System | 05 Oct 2020 00:01:30 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8d077e0f-7dd6-453a-9287-25e89620b44d' User entered '04 Oct 2020 20:01' | System | 05 Oct 2020 00:01:30 |
| | System | 05 Oct 2020 00:01:30 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:17', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered 'None (0)' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:20', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered 'None (0)' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered 'None (0)' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:26', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered 'None (0)' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:29', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered 'None (0)' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered 'None (0)' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered 'No (N)' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T12:59:39', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7b73d542-f419-4c0e-be36-24621c17aa11' User entered '28 Sep 2020 12:59' | System | 28 Sep 2020 16:59:42 |
| | System | 28 Sep 2020 16:59:42 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 12:43' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 15:13' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|---------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:10', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' User entered 'None (0)' | System | 28 Sep 2020 22:43:33 |
| | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' User entered 'None (0)' | System | 28 Sep 2020 22:43:33 |
| | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:17', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' User entered 'None (0)' | System | 28 Sep 2020 22:43:33 |
| | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:20', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' User entered 'None (0)' | System | 28 Sep 2020 22:43:33 |
| | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' User entered 'None (0)' | System | 28 Sep 2020 22:43:33 |
| | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' User entered 'None (0)' | System | 28 Sep 2020 22:43:33 |
| | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' | System | 28 Sep 2020 22:43:33 |
| User entered 'No (N)' | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-28T18:43:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '69122b28-0803-49c3-8116-802067fb2693' User entered '28 Sep 2020 18:43' | System | 28 Sep 2020 22:43:33 |
| | System | 28 Sep 2020 22:43:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '28 Sep 2020 16:08' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '29 Sep 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 2' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:05', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' User entered 'None (0)' | System | 29 Sep 2020 19:53:33 |
| | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:08', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' | System | 29 Sep 2020 19:53:33 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' | System | 29 Sep 2020 19:53:33 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:20', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' User entered 'None (0)' | System | 29 Sep 2020 19:53:33 |
| | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' User entered 'None (0)' | System | 29 Sep 2020 19:53:33 |
| | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:25', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' User entered 'None (0)' | System | 29 Sep 2020 19:53:33 |
| | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:28', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' | System | 29 Sep 2020 19:53:33 |
| User entered 'No (N)' | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-29T15:53:30', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ccf58133-cb9f-4f13-aace-c9f3737fecb4' User entered '29 Sep 2020 15:53' | System | 29 Sep 2020 19:53:33 |
| | System | 29 Sep 2020 19:53:33 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 3' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:49', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' | System | 30 Sep 2020 21:25:14 |
| User entered 'No interference with activity (1)' | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:52', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' | System | 30 Sep 2020 21:25:14 |
| User entered 'No interference with activity (1)' | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:24:57', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' User entered 'None (0)' | System | 30 Sep 2020 21:25:14 |
| | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:25:02', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' User entered 'None (0)' | System | 30 Sep 2020 21:25:14 |
| | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:25:04', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' User entered 'None (0)' | System | 30 Sep 2020 21:25:14 |
| | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:25:07', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' User entered 'None (0)' | System | 30 Sep 2020 21:25:14 |
| | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:25:10', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' User entered 'No (N)' | System | 30 Sep 2020 21:25:14 |
| | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-09-30T17:25:13', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e4083724-f52b-417b-a3e2-6cac3b367ad0' User entered '30 Sep 2020 17:25' | System | 30 Sep 2020 21:25:14 |
| | System | 30 Sep 2020 21:25:14 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 4' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:42', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' | System | 02 Oct 2020 13:23:06 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:46', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' User entered 'None (0)' | System | 02 Oct 2020 13:23:06 |
| | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:50', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' User entered 'None (0)' | System | 02 Oct 2020 13:23:06 |
| | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:52', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' User entered 'None (0)' | System | 02 Oct 2020 13:23:06 |
| | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:54', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' User entered 'None (0)' | System | 02 Oct 2020 13:23:06 |
| | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:22:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' User entered 'None (0)' | System | 02 Oct 2020 13:23:06 |
| | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:23:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' User entered 'No (N)' | System | 02 Oct 2020 13:23:06 |
| | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-02T09:23:02', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd01524a5-ca8b-41b4-81f9-4999e7c5de4c' User entered '02 Oct 2020 09:23' | System | 02 Oct 2020 13:23:06 |
| | System | 02 Oct 2020 13:23:06 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '01 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 5' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:51', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered 'None (0)' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:53', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered 'None (0)' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered 'None (0)' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:06:58', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered 'None (0)' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:07:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered 'None (0)' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:07:02', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered 'None (0)' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:07:06', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered 'No (N)' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T10:07:09', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'ce68c640-5566-4cd2-aa61-5078e5e56d6e' User entered '03 Oct 2020 10:07' | System | 03 Oct 2020 14:07:12 |
| | System | 03 Oct 2020 14:07:12 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '02 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 6' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:57:59', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered 'None (0)' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:58:01', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered 'None (0)' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:58:04', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered 'None (0)' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:58:07', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered 'None (0)' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:58:09', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered 'None (0)' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:58:11', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered 'None (0)' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:58:14', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered 'No (N)' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-03T19:58:17', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '8203e880-c715-443e-bf24-407f68e8dea9' User entered '03 Oct 2020 19:58' | System | 03 Oct 2020 23:58:18 |
| | System | 03 Oct 2020 23:58:18 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '03 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 28 Sep 2020 16:52:39 |
| User entered 'Day 7' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

HEADACHE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:35', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' | System | 05 Oct 2020 00:01:59 |
| User entered 'No interference with activity (1)' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

FATIGUE

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:39', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' User entered 'None (0)' | System | 05 Oct 2020 00:01:59 |
| | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:43', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' User entered 'None (0)' | System | 05 Oct 2020 00:01:59 |
| | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:46', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' User entered 'None (0)' | System | 05 Oct 2020 00:01:59 |
| | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:48', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' User entered 'None (0)' | System | 05 Oct 2020 00:01:59 |
| | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

CHILLS

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:50', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' User entered 'None (0)' | System | 05 Oct 2020 00:01:59 |
| | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:54', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' User entered 'No (N)' | System | 05 Oct 2020 00:01:59 |
| | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-10-04T20:01:56', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5e38a0b6-703f-4aad-b690-f29eb4933247' User entered '04 Oct 2020 20:01' | System | 05 Oct 2020 00:01:59 |
| | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '04 Oct 2020 12:00' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Oct 2020 11:59' | System | 28 Sep 2020 16:52:39 |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 05 Oct 2020 00:01:59 |
| User entered 'Day 8' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Oct 2020 12:00' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Oct 2020 11:59' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 05 Oct 2020 00:01:59 |
| User entered 'Day 9' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:17:10

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Oct 2020 12:00' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '07 Oct 2020 11:59' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 05 Oct 2020 00:01:59 |
| User entered 'Day 8' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '05 Oct 2020 12:00' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Oct 2020 11:59' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 05 Oct 2020 00:01:59 |
| User entered 'Day 9' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:17:10

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| | | |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:17:10

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '06 Oct 2020 12:00' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:17:10

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| User entered '07 Oct 2020 11:59' | System | 05 Oct 2020 00:01:59 |

US3672388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 07 Oct 2020 19:52:13 |

US3672388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '05 Oct 2020' | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 19:52:13 |

US3672388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 07 Oct 2020 19:52:13 |

US3672388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 07 Oct 2020 19:52:13 |

US3672388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 19:52:17 |

US3672388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 07 Oct 2020 19:52:17 |

US3672388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 22:54:39 |

US3672388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered '12 Oct 2020' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 22:54:39 |

US3672388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 22:54:39 |

US3672388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 12 Oct 2020 22:54:39 |

US3672388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 22:54:41 |

US3672388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 12 Oct 2020 22:54:41 |

US3672388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 20:32:48 |

US3672388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) | 19 Oct 2020 20:33:14 |
| Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' | System | 19 Oct 2020 20:33:14 |
| answered by data change (Site from System). | | |
| User entered '19 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Oct 2020 20:33:14 |
| User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 19 Oct 2020 20:32:48 |
| User entered '16 Oct 2020' | (b) (4), (b) (6) | 19 Oct 2020 20:32:48 |

US3672388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 19 Oct 2020 20:32:48 |

US3672388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered empty. | (b) (4), (b) (6) | 19 Oct 2020 20:32:48 |

US3672388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Oct 2020 20:33:20 |

US3672388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 19 Oct 2020 20:33:20 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:00:49 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Oct 2020' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:00:49 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:00:49 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'VISIT3' | System | 28 Oct 2020 16:00:49 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '28 Oct 2020' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '10:56' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '28 Oct 2020 10:56' | System | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '97.7' F | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '72' | (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'bpm' | System | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '15' | (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'breaths/min' | System | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '111' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '77' | (b) (4), (b) (6) | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'mmHg' | System | 28 Oct 2020 16:01:30 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| | | |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| | | |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:35 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:01:35 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:03:40 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is recorded under Visit 3 Day 57 in EDC, however immunogenicity sample is reported under Unscheduled visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 10:08:23 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is recorded under Visit 3 Day 57 in EDC, however immunogenicity sample is reported under Unscheduled visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' answered with 'visit date has been corrected by PPD. ' (Site from DM). | (b) (4), (b) (6) | 03 Dec 2020 22:01:26 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28OCT2020 is recorded under Visit 3 Day 57 in EDC, however immunogenicity sample is reported under Unscheduled visit in PPD portal. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM). | (b) (4), (b) (6) | 17 Nov 2020 10:01:42 |
| User entered '28 Oct 2020' | (b) (4), (b) (6) | 28 Oct 2020 16:03:40 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered '11:22' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:03:40 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '28 Oct 2020 11:22' | System | 28 Oct 2020 16:03:40 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 17 Feb 2021 21:08:45 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 16:03:47 |

US3672388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered '1' | System | 28 Oct 2020 16:03:47 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 64' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-03T17:44:32', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'b6ccae7e-2850-4bf2-9af6-504c05ad3dd8' | System | 03 Nov 2020 22:44:49 |
| User entered 'No (N)' | System | 03 Nov 2020 22:44:49 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-03T17:44:37', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'b6ccae7e-2850-4bf2-9af6-504c05ad3dd8' | System | 03 Nov 2020 22:44:49 |
| User entered 'No (N)' | System | 03 Nov 2020 22:44:49 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-03T17:44:44', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'b6ccae7e-2850-4bf2-9af6-504c05ad3dd8' User entered '03 Nov 2020 17:44:44' | System | 03 Nov 2020 22:44:49 |
| | System | 03 Nov 2020 22:44:49 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered '31 Oct 2020 00:01' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered '04 Nov 2020 23:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 71' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Chills](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Cough](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Fatigue](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Muscle aches](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Body aches](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Headache](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[New loss of taste](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[New loss of smell](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Sore throat](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Congestion](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Runny nose](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Nausea](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Vomiting](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Diarrhea](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered '07 Nov 2020 00:01' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 21:00:30 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered '11 Nov 2020 23:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered 'Day 78' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-17T18:12:41', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7527cec5-7d9a-4d56-956b-05764e96dd6a' User entered 'No (N)' | System | 17 Nov 2020 23:12:54 |
| | System | 17 Nov 2020 23:12:54 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-17T18:12:44', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7527cec5-7d9a-4d56-956b-05764e96dd6a' | System | 17 Nov 2020 23:12:54 |
| User entered 'No (N)' | System | 17 Nov 2020 23:12:54 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-17T18:12:48', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7527cec5-7d9a-4d56-956b-05764e96dd6a' User entered '17 Nov 2020 18:12:48' | System | 17 Nov 2020 23:12:54 |
| | System | 17 Nov 2020 23:12:54 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered '14 Nov 2020 00:01' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 07:49:31 |
| Data entry locked. | System | 31 Aug 2020 17:26:28 |
| User entered '18 Nov 2020 23:59' | System | 31 Aug 2020 17:26:28 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-28T08:52:24', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1eea7776-f6ab-439a-9103-029ab57aafd9' User entered 'No (N)' | System | 28 Nov 2020 13:52:44 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-28T08:52:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1eea7776-f6ab-439a-9103-029ab57aafd9' User entered 'No (N)' | System | 28 Nov 2020 13:52:44 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-11-28T08:52:42', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '1eea7776-f6ab-439a-9103-029ab57aafd9' User entered '28 Nov 2020 08:52:42' | System | 28 Nov 2020 13:52:44 |
| | System | 28 Nov 2020 13:52:44 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-04T12:03:23', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '72386eaf-a528-49fa-a0a6-7aab43a6d66c' User entered 'No (N)' | System | 04 Dec 2020 17:03:36 |
| | System | 04 Dec 2020 17:03:36 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-04T12:03:27', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '72386eaf-a528-49fa-a0a6-7aab43a6d66c' User entered 'No (N)' | System | 04 Dec 2020 17:03:36 |
| | System | 04 Dec 2020 17:03:36 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-04T12:03:33', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '72386eaf-a528-49fa-a0a6-7aab43a6d66c' User entered '04 Dec 2020 12:03:33' | System | 04 Dec 2020 17:03:36 |
| | System | 04 Dec 2020 17:03:36 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-09T12:05:59', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f99d3eef-2369-4bd7-8d6b-180ae8c80720' User entered 'No (N)' | System | 09 Dec 2020 17:06:12 |
| | System | 09 Dec 2020 17:06:12 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-09T12:06:04', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f99d3eef-2369-4bd7-8d6b-180ae8c80720' User entered 'No (N)' | System | 09 Dec 2020 17:06:12 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-09T12:06:08', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'f99d3eef-2369-4bd7-8d6b-180ae8c80720' User entered '09 Dec 2020 12:06:08' | System | 09 Dec 2020 17:06:12 |
| | System | 09 Dec 2020 17:06:12 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-16T10:30:13', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7e44064d-abfa-4d0e-bdbc-f9ed1e6c7ac5' User entered 'No (N)' | System | 16 Dec 2020 15:30:30 |
| | System | 16 Dec 2020 15:30:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-16T10:30:19', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7e44064d-abfa-4d0e-bdbc-f9ed1e6c7ac5' User entered 'No (N)' | System | 16 Dec 2020 15:30:30 |
| | System | 16 Dec 2020 15:30:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-16T10:30:27', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '7e44064d-abfa-4d0e-bdbc-f9ed1e6c7ac5' User entered '16 Dec 2020 10:30:27' | System | 16 Dec 2020 15:30:30 |
| | System | 16 Dec 2020 15:30:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-24T08:48:52', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '61f60b74-21e6-4115-909a-916a9af76747' User entered 'No (N)' | System | 24 Dec 2020 13:49:15 |
| | System | 24 Dec 2020 13:49:15 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-24T08:49:09', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '61f60b74-21e6-4115-909a-916a9af76747' User entered 'No (N)' | System | 24 Dec 2020 13:49:15 |
| | System | 24 Dec 2020 13:49:15 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-24T08:49:12', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '61f60b74-21e6-4115-909a-916a9af76747' User entered '24 Dec 2020 08:49:12' | System | 24 Dec 2020 13:49:15 |
| | System | 24 Dec 2020 13:49:15 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-30T10:50:01', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5b58e46e-8cbe-4aa7-a91b-15b75672ef90' User entered 'No (N)' | System | 30 Dec 2020 15:50:11 |
| | System | 30 Dec 2020 15:50:11 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-30T10:50:05', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5b58e46e-8cbe-4aa7-a91b-15b75672ef90' User entered 'No (N)' | System | 30 Dec 2020 15:50:11 |
| | System | 30 Dec 2020 15:50:11 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2020-12-30T10:50:09', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '5b58e46e-8cbe-4aa7-a91b-15b75672ef90' User entered '30 Dec 2020 10:50:09' | System | 30 Dec 2020 15:50:11 |
| | System | 30 Dec 2020 15:50:11 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-08T12:41:53', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '316939ea-e9f1-4aed-a1de-c45a13d9dff4' User entered 'No (N)' | System | 08 Jan 2021 17:42:06 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-08T12:41:57', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '316939ea-e9f1-4aed-a1de-c45a13d9dff4' User entered 'No (N)' | System | 08 Jan 2021 17:42:06 |
| | System | 08 Jan 2021 17:42:06 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-08T12:42:01', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '316939ea-e9f1-4aed-a1de-c45a13d9dff4' User entered '08 Jan 2021 12:42:01' | System | 08 Jan 2021 17:42:06 |
| | System | 08 Jan 2021 17:42:06 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-15T12:00:40', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '9e80ca75-7631-4120-b7fb-d6c01d375014' User entered 'No (N)' | System | 15 Jan 2021 17:01:27 |
| | System | 15 Jan 2021 17:01:27 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-15T12:00:43', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '9e80ca75-7631-4120-b7fb-d6c01d375014' User entered 'No (N)' | System | 15 Jan 2021 17:01:27 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-15T12:00:52', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '9e80ca75-7631-4120-b7fb-d6c01d375014' User entered '15 Jan 2021 12:00:52' | System | 15 Jan 2021 17:01:27 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-20T15:24:30', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6a270bf8-d7db-4da2-bbb9-439b4053976b' User entered 'No (N)' | System | 20 Jan 2021 20:24:40 |
| | System | 20 Jan 2021 20:24:40 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-20T15:24:33', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6a270bf8-d7db-4da2-bbb9-439b4053976b' User entered 'No (N)' | System | 20 Jan 2021 20:24:40 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-20T15:24:36', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6a270bf8-d7db-4da2-bbb9-439b4053976b' User entered '20 Jan 2021 15:24:36' | System | 20 Jan 2021 20:24:40 |
| | System | 20 Jan 2021 20:24:40 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-27T07:42:35', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '530020f8-a831-401c-841e-a01badc52e3c' User entered 'No (N)' | System | 27 Jan 2021 12:42:46 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-27T07:42:41', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '530020f8-a831-401c-841e-a01badc52e3c' User entered 'No (N)' | System | 27 Jan 2021 12:42:46 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-01-27T07:42:45', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '530020f8-a831-401c-841e-a01badc52e3c' User entered '27 Jan 2021 07:42:45' | System | 27 Jan 2021 12:42:46 |
| | System | 27 Jan 2021 12:42:46 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-10T08:59:24', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd202069a-3123-436a-b1a1-e52b4b7984b5' User entered 'No (N)' | System | 10 Feb 2021 13:59:38 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-10T08:59:31', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd202069a-3123-436a-b1a1-e52b4b7984b5' | System | 10 Feb 2021 13:59:38 |
| User entered 'No (N)' | System | 10 Feb 2021 13:59:38 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-10T08:59:35', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'd202069a-3123-436a-b1a1-e52b4b7984b5' | System | 10 Feb 2021 13:59:38 |
| User entered '10 Feb 2021 08:59:35' | System | 10 Feb 2021 13:59:38 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-17T13:45:43', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a59204b8-e43a-4494-b0e2-5bd9c5c7ee41' User entered 'No (N)' | System | 18 Feb 2021 18:57:55 |
| | System | 18 Feb 2021 18:57:55 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-17T13:45:46', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a59204b8-e43a-4494-b0e2-5bd9c5c7ee41' | System | 18 Feb 2021 18:57:55 |
| User entered 'No (N)' | System | 18 Feb 2021 18:57:55 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-17T13:45:49', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'a59204b8-e43a-4494-b0e2-5bd9c5c7ee41' User entered '17 Feb 2021 13:45:49' | System | 18 Feb 2021 18:57:55 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-24T09:16:22-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '24351ce2-d944-4f79-83c9-ab0b9074092a' User entered 'No (N)' | System | 24 Feb 2021 14:16:36 |
| | System | 24 Feb 2021 14:16:36 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-24T09:16:26-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '24351ce2-d944-4f79-83c9-ab0b9074092a' User entered 'No (N)' | System | 24 Feb 2021 14:16:36 |
| | System | 24 Feb 2021 14:16:36 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-02-24T09:16:31-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '24351ce2-d944-4f79-83c9-ab0b9074092a' User entered '24 Feb 2021 14:16:31' | System | 24 Feb 2021 14:16:36 |
| | System | 24 Feb 2021 14:16:36 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-07T10:41:38-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e229feee-0032-4426-8016-25a70bfa9c3a' | System | 07 Mar 2021 15:41:58 |
| User entered 'No (N)' | System | 07 Mar 2021 15:41:58 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-07T10:41:48-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e229feee-0032-4426-8016-25a70bfa9c3a' | System | 07 Mar 2021 15:41:58 |
| User entered 'No (N)' | System | 07 Mar 2021 15:41:58 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-07T10:41:55-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'e229feee-0032-4426-8016-25a70bfa9c3a' User entered '07 Mar 2021 10:41:55' | System | 07 Mar 2021 15:41:58 |
| | System | 07 Mar 2021 15:41:58 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-13T17:56:49-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'bd254571-3cb9-4cb6-92a5-aba3f6bf146d' | System | 13 Mar 2021 22:56:58 |
| User entered 'No (N)' | System | 13 Mar 2021 22:56:58 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-13T17:56:52-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'bd254571-3cb9-4cb6-92a5-aba3f6bf146d' | System | 13 Mar 2021 22:56:58 |
| User entered 'No (N)' | System | 13 Mar 2021 22:56:58 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-13T17:56:56-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: 'bd254571-3cb9-4cb6-92a5-aba3f6bf146d' User entered '13 Mar 2021 17:56:56' | System | 13 Mar 2021 22:56:58 |
| | System | 13 Mar 2021 22:56:58 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-18T13:02:21-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '535e098d-0556-4f09-b7da-a70a29328962' User entered 'No (N)' | System | 18 Mar 2021 17:05:12 |
| | System | 18 Mar 2021 17:05:12 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-18T13:02:25-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '535e098d-0556-4f09-b7da-a70a29328962' | System | 18 Mar 2021 17:05:12 |
| User entered 'No (N)' | System | 18 Mar 2021 17:05:12 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-18T13:02:28-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '535e098d-0556-4f09-b7da-a70a29328962' User entered '18 Mar 2021 13:02:28' | System | 18 Mar 2021 17:05:12 |
| | System | 18 Mar 2021 17:05:12 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-24T20:44:42-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0b93f985-1712-4677-a2ee-a1f417fc79bb' | System | 25 Mar 2021 00:44:54 |
| User entered 'No (N)' | System | 25 Mar 2021 00:44:54 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-24T20:44:46-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0b93f985-1712-4677-a2ee-a1f417fc79bb' | System | 25 Mar 2021 00:44:54 |
| User entered 'No (N)' | System | 25 Mar 2021 00:44:54 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-24T20:44:50-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '0b93f985-1712-4677-a2ee-a1f417fc79bb' User entered '24 Mar 2021 20:44:50' | System | 25 Mar 2021 00:44:54 |
| | System | 25 Mar 2021 00:44:54 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-03T09:40:24-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '9ae6cf54-b301-464a-87d1-a3eaf78c069' User entered 'No (N)' | System | 03 Apr 2021 13:40:38 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-03T09:40:28-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '9ae6cf54-b301-464a-87d1-a3eaf78c069' User entered 'No (N)' | System | 03 Apr 2021 13:40:38 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-03T09:40:32-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '9ae6cf54-b301-464a-87d1-a3eaf78c069' | System | 03 Apr 2021 13:40:38 |
| User entered '03 Apr 2021 09:40:32' | System | 03 Apr 2021 13:40:38 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-09T11:49:55-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '2a702ebd-35bc-4cf5-8882-9591881bb086' User entered 'No (N)' | System | 09 Apr 2021 15:50:08 |
| | System | 09 Apr 2021 15:50:08 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-09T11:49:58-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '2a702ebd-35bc-4cf5-8882-9591881bb086' User entered 'No (N)' | System | 09 Apr 2021 15:50:08 |
| | System | 09 Apr 2021 15:50:08 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-09T11:50:03-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '2a702ebd-35bc-4cf5-8882-9591881bb086' | System | 09 Apr 2021 15:50:08 |
| User entered '09 Apr 2021 11:50:03' | System | 09 Apr 2021 15:50:08 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-14T07:29:10-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6966ef00-a230-44db-9123-85a865b3c921' User entered 'No (N)' | System | 14 Apr 2021 13:56:41 |
| | System | 14 Apr 2021 13:56:41 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-14T07:29:15-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6966ef00-a230-44db-9123-85a865b3c921' | System | 14 Apr 2021 13:56:41 |
| User entered 'No (N)' | System | 14 Apr 2021 13:56:41 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-14T07:29:18-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '6966ef00-a230-44db-9123-85a865b3c921' | System | 14 Apr 2021 13:56:41 |
| User entered '14 Apr 2021 07:29:18' | System | 14 Apr 2021 13:56:41 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-21T17:02:46-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '3394e576-6375-478b-a60d-b1c35b8cbfab' User entered 'No (N)' | System | 21 Apr 2021 21:02:59 |
| | System | 21 Apr 2021 21:02:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-21T17:02:49-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '3394e576-6375-478b-a60d-b1c35b8cbfab' User entered 'No (N)' | System | 21 Apr 2021 21:02:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-21T17:02:54-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '3394e576-6375-478b-a60d-b1c35b8cbfab' User entered '21 Apr 2021 17:02:54' | System | 21 Apr 2021 21:02:59 |
| | System | 21 Apr 2021 21:02:59 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-30T12:15:59-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '72ef4f16-6a34-45b0-8857-06f3414319af' | System | 30 Apr 2021 16:28:08 |
| User entered 'No (N)' | System | 30 Apr 2021 16:28:08 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

Have you been exposed to someone with 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 (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-30T12:16:03-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '72ef4f16-6a34-45b0-8857-06f3414319af' | System | 30 Apr 2021 16:28:08 |
| User entered 'No (N)' | System | 30 Apr 2021 16:28:08 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-04-30T12:16:07-04:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '72ef4f16-6a34-45b0-8857-06f3414319af' | System | 30 Apr 2021 16:28:08 |
| User entered '30 Apr 2021 12:16:07' | System | 30 Apr 2021 16:28:08 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '26 Oct 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '30 Oct 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

TIMEPOINT

| Audit | User | Time (GMT) |
|-------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '02 Nov 2022 00:01' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:10

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:00:30 |
| Amendment Manager: User entered '06 Nov 2022 23:59' | System | 19 Nov 2020 21:00:30 |

US3672388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:17:10

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 13:53:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-01T16:16:47-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '80ca8ad1-8865-4b43-86a1-725ce1779e8a' User entered 'Yes (Y)' | System | 01 Mar 2021 21:17:15 |
| | System | 01 Mar 2021 21:17:15 |

US3672388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:17:10

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?

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-01T16:16:55-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '80ca8ad1-8865-4b43-86a1-725ce1779e8a' User entered 'No (N)' | System | 01 Mar 2021 21:17:15 |
| | System | 01 Mar 2021 21:17:15 |

US3672388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:17:10

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 13:53:00 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DB4AA5-F9B8-4FAA-896B-B28C9794FD85)', Time: '2021-03-01T16:17:04-05:00', User OID: 'PatientReportedOutcome (US3672388)', ODM File OID: '80ca8ad1-8865-4b43-86a1-725ce1779e8a' User entered '01 Mar 2021 16:17:04' | System | 01 Mar 2021 21:17:15 |
| | System | 01 Mar 2021 21:17:15 |

US3672388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 21:35:49 |

US3672388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '23 Nov 2020' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 21:35:49 |

US3672388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 21:35:49 |

US3672388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 21:35:49 |

US3672388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 21:35:59 |

US3672388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 21:39:45 |
| User entered 'I' | System | 23 Nov 2020 21:35:59 |

US3672388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Dec 2020 12:51:27 |

US3672388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '29 Dec 2020' | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 12:51:27 |

US3672388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 12:51:27 |

US3672388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 12:51:27 |

US3672388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Dec 2020 12:51:31 |

US3672388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User entered 'I' | System | 30 Dec 2020 12:51:31 |

US3672388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Jan 2021 21:16:57 |

US3672388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:16:57 |

US3672388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 28 Jan 2021 21:16:57 |

US3672388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:16:57 |

US3672388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Jan 2021 21:18:12 |

US3672388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User entered 'I' | System | 28 Jan 2021 21:18:12 |

US3672388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Feb 2021 21:57:46 |

US3672388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '23 Feb 2021' | (b) (4), (b) (6) | 24 Feb 2021 21:57:46 |

US3672388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 24 Feb 2021 21:57:46 |

US3672388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered empty. | (b) (4), (b) (6) | 24 Feb 2021 21:57:46 |

US3672388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Feb 2021 21:57:52 |

US3672388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 23:23:55 |
| User entered 'I' | System | 24 Feb 2021 21:57:52 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 18:57:12 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered '16 Mar 2021' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 18:57:12 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[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 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 18:57:12 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered 'VISIT4' | System | 17 Mar 2021 18:57:12 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered empty. | System | 31 Mar 2021 20:17:58 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| | | |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:10

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| | | |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 18:57:22 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:10

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered empty. | (b) (4), (b) (6) | 17 Mar 2021 18:57:22 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Mar 2021 18:57:50 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered '16 Mar 2021' | (b) (4), (b) (6) | 17 Mar 2021 18:57:50 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered '11:22' | (b) (4), (b) (6) | 17 Mar 2021 18:57:50 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '16 Mar 2021 11:22' | System | 17 Mar 2021 18:57:50 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 17 Mar 2021 18:58:01 |

US3672388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 17:10:26 |
| User entered '1' | System | 17 Mar 2021 18:58:01 |

US3672388

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 18:52:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 16:36:20 |

US3672388

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 18:52:01 |
| User entered '23 Apr 2021' | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 16:36:20 |

US3672388

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 18:52:01 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 16:36:20 |

US3672388

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:10

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 18:52:01 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 16:36:20 |

US3672388

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 23 Apr 2021 18:52:01 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 23 Apr 2021 16:36:23 |

US3672388

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:10

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 23 Apr 2021 16:36:23 |

US3672388

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

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:26:53 |

US3672388

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

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '21 Jan 2021' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:26:53 |

US3672388

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

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:26:53 |

US3672388

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

Form: Visit Date

Generated On: 10 Jun 2021 09:17:10

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User entered 'UNBLND_DECIDE' | System | 22 Jan 2021 20:26:53 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '21 Jan 2021' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:27:22 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 16:44:12 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 07:37:26 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:27:22 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User closed query 'Per CDM, per sponsor review: 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) | 14 Apr 2021 13:16:47 |
| Query 'Per CDM, per sponsor review: 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) | 12 Apr 2021 16:45:13 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | (b) (4), (b) (6) | 12 Apr 2021 16:44:12 |
| User opened query 'Per CDM, per sponsor review: 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 09:44:31 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 07:37:26 |

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '21 Jan 2021' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:27:22 |

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:27:22 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6) | 22 Jan 2021 20:27:22 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6) | 22 Jan 2021 20:27:22 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:27:22 |

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User entered empty. | System | 22 Jan 2021 20:27:22 |

US3672388

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:10

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User entered empty. | System | 22 Jan 2021 20:27:22 |

US3672388

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:27:51 |

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '21 Jan 2021' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:27:51 |

US3672388

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '11:27' | (b) (4), (b) (6) | 22 Jan 2021 20:27:51 |

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User entered '21 Jan 2021 11:27' | System | 22 Jan 2021 20:27:51 |

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:17:10

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:28:08 |

US3672388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:17:10

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '21 Jan 2021' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 20:28:08 |

US3672388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:17:10

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '11:08' | (b) (4), (b) (6) | 22 Jan 2021 20:28:08 |

US3672388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:55:21 |
| User entered '21 Jan 2021 11:08' | System | 22 Jan 2021 20:28:08 |

US3672388

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:17:10

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:06:39 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 16:12:52 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Adverse event](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:19 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Mar 2021 20:01:43 |
| User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 18:07:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 18:07:45 |
| Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'Updated' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 18:06:58 |
| Data point term sent to Coder | System | 03 Mar 2021 18:06:28 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Mar 2021 18:06:27 |
| User entered 'GERD' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Mar 2021 18:06:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:12 |
| User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM). | (b) (4), (b) (6) | 18 Feb 2021 16:29:14 |
| User closed query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 08:30:43 |
| Data point term sent to Coder | System | 02 Feb 2021 20:06:21 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Adverse event](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Un-verified. | Patty Howenstine (b) (4) | 02 Feb 2021 20:06:13 |
| Coding entries removed. | Patty Howenstine (b) (4) | 02 Feb 2021 20:06:13 |
| User entered 'NON- CARDIAC Intermittent SUBSTERNAL PRESSURE' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 02 Feb 2021 20:06:13 |
| Query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. | Patty Howenstine (b) (4) | 02 Feb 2021 20:05:38 |
| ' answered with 'Was not assessed for potential COVID-19 infection. Reports pressure lasts about 45 minutes and resolves without interventions. No other symptoms. F/U with PCP with normal EKG. Thought maybe a muscle strain. Was to f/u with cardiology. ' (Site from DM). | | |
| User opened query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. | (b) (4), (b) (6) | 02 Feb 2021 12:10:26 |
| ' (Site from DM). | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:03 |
| User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if SUBSTERNAL PRESSURE is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. | (b) (4), (b) (6) | 18 Dec 2020 16:25:12 |
| ' (Site from DM). | | |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Substernal pain - version MedDRA\23.0. | Coder Import (b) (4) | 17 Dec 2020 17:49:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 17 Dec 2020 17:49:44 |

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Adverse event](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if SUBSTERNAL PRESSURE is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'reconciled ' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 17:45:30 |
| Data point term sent to Coder | System | 17 Dec 2020 17:45:21 |
| Coding entries removed. | (b) (4), (b) (6) | 17 Dec 2020 17:45:20 |
| User entered 'NON- CARDIAC SUBSTERNAL PRESSURE' reason for change: Data Entry Error | (b) (4), (b) (6) | 17 Dec 2020 17:45:20 |
| User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if SUBSTERNAL PRESSURE is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. | (b) (4), (b) (6) | 28 Nov 2020 15:11:58 |
| ' (Site from DM). | | |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest pressure - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Nov 2020 12:11:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 11 Nov 2020 12:11:29 |
| Data point term sent to Coder | System | 28 Oct 2020 16:34:01 |
| User entered 'Substernal pressure' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:06 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:07 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:19 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| Query 'Data entered is non-conformant. Please correct.' canceled (Site from System). | (b) (4), (b) (6) | 07 Apr 2021 15:04:49 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:44 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:44 |
| User entered 'UN Sep 2020' (non-conformant). | (b) (4), (b) (6) | 04 Mar 2021 13:30:44 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:32 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:32 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 04 Mar 2021 13:30:32 |
| User entered ' Sep 2020' (non-conformant). | (b) (4), (b) (6) | 04 Mar 2021 13:30:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Feb 2021 13:41:45 |
| User closed query 'Per source, the start day is unknown. Please verify and update to UN-Sep-2020 accordingly' (Site from CRA). | (b) (4), (b) (6) | 19 Feb 2021 13:41:38 |
| Query 'Per source, the start day is unknown. Please verify and update to UN-Sep-2020 accordingly' answered with 'done' (Site from CRA). | Patty Howenstine (b) (4) | 02 Feb 2021 20:05:57 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 02 Feb 2021 20:05:50 |
| User entered 'un Sep 2020' (non-conformant). | Patty Howenstine (b) (4) | 02 Feb 2021 20:05:50 |
| User opened query 'Per source, the start day is unknown. Please verify and update to UN-Sep-2020 accordingly' (Site from CRA). | (b) (4), (b) (6) | 28 Jan 2021 17:09:59 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Oct 2020 18:21:59 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Oct 2020 18:21:36 |
| User entered '01 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Oct 2020 18:21:36 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Oct 2020 18:20:27 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Oct 2020 18:20:27 |
| User entered 'UN Sep 2020' (non-conformant). | (b) (4), (b) (6) | 28 Oct 2020 18:20:27 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Oct 2020 16:36:43 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Oct 2020 16:36:43 |
| User entered 'Sep 2020' (non-conformant). | (b) (4), (b) (6) | 28 Oct 2020 16:36:43 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 28 Oct 2020 16:33:30 |
| User entered 'UN Sep 2020' (non-conformant). | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | 28 Jan 2021 17:12:10 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 28 Oct 2020 18:21:59 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 28 Oct 2020 18:21:36 |
| User entered empty. | System | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User entered empty. | System | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Feb 2021 13:41:51 |
| User closed query 'Per source, please update this to NO. end date in source is UN-OCT-2020. ' (Site from CRA). | (b) (4), (b) (6) | 19 Feb 2021 13:41:49 |
| User closed query 'Per DM CLR: RQ: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 17:04:27 |
| Query 'Per source, please update this to NO. end date in source is UN-OCT-2020. ' answered with 'done' (Site from CRA). | Patty Howenstine (b) (4) | 02 Feb 2021 20:06:23 |
| Query 'Per DM CLR: RQ: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with 'done' (Site from DM). | Patty Howenstine (b) (4) | 02 Feb 2021 20:06:19 |
| User entered 'No (N)' reason for change: Data Entry Error | Patty Howenstine (b) (4) | 02 Feb 2021 20:05:33 |
| User opened query 'Per source, please update this to NO. end date in source is UN-OCT-2020. ' (Site from CRA). | (b) (4), (b) (6) | 28 Jan 2021 17:11:00 |
| User opened query 'Per DM CLR: RQ: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM). | (b) (4), (b) (6) | 14 Jan 2021 10:31:33 |

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 18 Dec 2020 16:25:41 |
| Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'confirm still ongoing ' (Site from DM). | (b) (4), (b) (6) | 17 Dec 2020 17:45:15 |
| User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM). | (b) (4), (b) (6) | 30 Nov 2020 01:17:33 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:19 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| Query 'Data entered is non-conformant. Please correct.' canceled (Site from System). | (b) (4), (b) (6) | 07 Apr 2021 15:04:51 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:44 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:44 |
| User entered 'UN Oct 2020' (non-conformant). | (b) (4), (b) (6) | 04 Mar 2021 13:30:44 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:32 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Mar 2021 13:30:32 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 04 Mar 2021 13:30:32 |
| User entered ' Oct 2020' (non-conformant). | (b) (4), (b) (6) | 04 Mar 2021 13:30:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Feb 2021 13:41:58 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 02 Feb 2021 20:05:33 |
| DataPoint Un-verified. | Patty Howenstine (b) (4) | 02 Feb 2021 20:05:33 |
| User entered 'un Oct 2020' (non-conformant). | Patty Howenstine (b) (4) | 02 Feb 2021 20:05:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:13 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:14 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User entered empty. | System | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Severity](#)

| Audit | User | Time (GMT) |
|--------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:16 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:20 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:12:59 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:01 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:02 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:04 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:06 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

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[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:07 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:09 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:10 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:12 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:14 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:16 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:17 |
| User entered 'None (NONE)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:18 |
| User entered 'l' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:20 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

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Generated On: 10 Jun 2021 09:17:10

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:22 |
| User entered '0' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Outcome](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:12 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:24 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:13:26 |
| User entered empty. | (b) (4), (b) (6) | 28 Oct 2020 16:33:30 |

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User entered '0' | System | 28 Oct 2020 16:33:30 |

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| User entered 'I' | System | 28 Oct 2020 16:33:30 |

US3672388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:17:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 12:55:06 |
| | | |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Mar 2021 15:42:54 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 19 Mar 2021 15:42:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:16:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:21 |
| User entered | System | 22 Jan 2021 15:16:17 |
| 'USA-US116-2021-mRNA-1273-P301000004' | | |
| User entered 'New' | (b) (4), (b) (6) | 22 Jan 2021 15:16:17 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Adverse event](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM). Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'no worsening' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Apr 2021 07:10:01 |
| User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'no worsening' (Site from DM). | (b) (4), (b) (6) | 02 Apr 2021 19:31:04 |
| User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM). | (b) (4), (b) (6) | 01 Apr 2021 08:59:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:16:52 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 22 Jan 2021 18:54:03 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 22 Jan 2021 18:54:03 |
| Data point term sent to Coder | System | 21 Jan 2021 23:54:48 |
| User entered 'recurrent small bowel obstruction' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:16:54 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:12 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:10 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 14:10:12 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| User entered '01 Nov 2020' reason for change: New Information | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:16:48 |
| User entered '31 Oct 2020' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:15:09 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 21 Jan 2021 23:55:16 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Jan 2021 23:55:16 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 21 Jan 2021 23:55:16 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Jan 2021 23:54:45 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 21 Jan 2021 23:54:45 |
| User entered 'un:un' (non-conformant). | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|--------|----------------------|
| User entered empty. | System | 21 Jan 2021 23:55:16 |
| User entered '31 Oct 2020 UN:UN' (non-conformant). | System | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:07 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 13:56:16 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| User entered '04 Nov 2020' reason for change: New Information | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:15:06 |
| User entered '02 Nov 2020' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:15:29 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 21 Jan 2021 23:55:16 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Jan 2021 23:55:16 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 21 Jan 2021 23:55:16 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Jan 2021 23:54:45 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 21 Jan 2021 23:54:45 |
| User entered 'un:un' (non-conformant). | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------|--------|----------------------|
| User entered empty. | System | 21 Jan 2021 23:55:16 |
| User entered '02 Nov 2020 UN:UN' (non-conformant). | System | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Severity](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:17 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |
| | | |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:27 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:31 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:33 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:34 |
| User entered 'I' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 13:56:26 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| User entered '02 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:15:36 |
| User entered '01 Nov 2020' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | 25 Feb 2021 13:56:23 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| User entered '04 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:15:38 |
| User entered '02 Nov 2020' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:40 |
| User entered 'No (N)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:41 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |
| | | |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:42 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |
| | | |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:16:44 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:50 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:47 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:52 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:15:54 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:16:42 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:19 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User closed query 'Per DM CLR: Please review response as there are Concomitant Medications (#2 & 3) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | (b) (4), (b) (6) | 19 Mar 2021 07:24:34 |
| Query 'Per DM CLR: Please review response as there are Concomitant Medications (#2 & 3) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 18 Mar 2021 16:17:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 18 Mar 2021 16:17:48 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 18 Mar 2021 16:17:48 |
| User opened query 'Per DM CLR: Please review response as there are Concomitant Medications (#2 & 3) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM). | (b) (4), (b) (6) | 09 Mar 2021 12:08:01 |
| User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety). | (b) (4), (b) (6) | 03 Feb 2021 16:51:21 |
| Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'none' (Site from Safety). | Patty Howenstine (b) (4) | 02 Feb 2021 20:06:50 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Jan 2021 16:54:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:16:40 |
| User entered '0' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User closed query 'Per DM CLR: Please review response as the recorded porcedure is not therapeutic in nature rather it is more of diagnostic procedure. Update as appropriate. Otherwise, provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 10:26:01 |
| Query 'Per DM CLR: Please review response as the recorded porcedure is not therapeutic in nature rather it is more of diagnostic procedure. Update as appropriate. Otherwise, provide clarification.' | (b) (4), (b) (6) | 02 Apr 2021 19:32:14 |
| answered with 'please confirm which procedure you would like deleted' (Site from DM). | | |
| User opened query 'Per DM CLR: Please review response as the recorded porcedure is not therapeutic in nature rather it is more of diagnostic procedure. Update as appropriate. Otherwise, provide clarification.' | (b) (4), (b) (6) | 01 Apr 2021 09:00:09 |
| (Site from DM). | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:16:39 |
| User entered 'I' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Outcome](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:16:37 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:16:35 |
| User entered empty. | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |
| | | |

US3672388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:19 |
| User signature succeeded. | Cynthia Strout (b) (4) | 08 Apr 2021 21:51:10 |
| User closed query 'PV query: Please confirm the date when following laboratory tests blood sodium (NA), complete blood count (CBC), and mean corpuscular HGB was performed.' (Site from Safety). | (b) (4), (b) (6) | 05 Apr 2021 14:50:29 |
| Query 'PV query: Please confirm the date when following laboratory tests blood sodium (NA), complete blood count (CBC), and mean corpuscular HGB was performed.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 19:47:24 |
| User entered 'SUBJECT HAS MEDICAL HISTORY OF MULTIPLE SMALL BOWEL OBSTRUCTIONS. SUBJECT WENT TO ER ON 11/01/20 COMPLAINING OF ABDOMINAL PAIN, WAS SENT HOME. 11/02/2020 WENT BACK TO ED COMPLAINING OF ABDOMINAL PAIN AND NAUSEA - SHE RECEIVED A CT SCAN AND WAS DIAGNOSED WITH A SMALL BOWEL OBSTRUCTION AND WAS ADMITTED. SUBJECT RECEIVED NASOGASTRIC TUBE PROCEDURE AND WAS DISCHARGED ON 11/04/20. 11/4/2020 Labs: NA 134 CBC 16.1 MEAN CORPUSCULAR HGB 32.8' reason for change: Data Entry Error | (b) (4), (b) (6) | 02 Apr 2021 19:47:18 |
| User opened query 'PV query: Please confirm the date when following laboratory tests blood sodium (NA), complete blood count (CBC), and mean corpuscular HGB was performed.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 20:12:43 |
| Query '1. Please confirm the date when following laboratory tests blood sodium (NA), complete blood count (CBC), and mean corpuscular HGB was performed. ' canceled (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 20:12:34 |
| User opened query '1. Please confirm the date when following laboratory tests blood sodium (NA), complete blood count (CBC), and mean corpuscular HGB was performed. ' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 13:51:33 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Narrative](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'Please clarify if the subject went to ER on 31 Oct 2020 or 01 Nov 2020. If the subject went to ER on 31 Oct 2020, please correct the event onset date accordingly.' (Site from Safety). | (b) (4), (b) (6) | 04 Mar 2021 13:35:37 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 04 Mar 2021 13:35:31 |
| Query 'Please clarify if the subject went to ER on 31 Oct 2020 or 01 Nov 2020. If the subject went to ER on 31 Oct 2020, please correct the event onset date accordingly.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 03 Mar 2021 18:03:59 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6) | 03 Mar 2021 18:03:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Mar 2021 18:03:51 |
| User entered 'SUBJECT HAS MEDICAL HISTORY OF MULTIPLE SMALL BOWEL OBSTRUCTIONS. SUBJECT WENT TO ER ON 11/01/20 COMPLAINING OF ABDOMINAL PAIN, WAS SENT HOME. 11/02/2020 WENT BACK TO ED COMPLAINING OF ABDOMINAL PAIN AND NAUSEA - SHE RECEIVED A CT SCAN AND WAS DIAGNOSED WITH A SMALL BOWEL OBSTRUCTION AND WAS ADMITTED. SUBJECT RECEIVED NASOGASTRIC TUBE PROCEDURE AND WAS DISCHARGED ON 11/04/20. | (b) (4), (b) (6) | 03 Mar 2021 18:03:51 |
| Na 134 CBC 16.1 MEAN CORPUSCULAR HGB 32.8' reason for change: Data Entry Error DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:10:12 |
| User opened query 'Please clarify if the subject went to ER on 31 Oct 2020 or 01 Nov 2020. If the subject went to ER on 31 Oct 2020, please correct the event onset date accordingly.' (Site from Safety). | (b) (4), (b) (6) | 22 Feb 2021 12:15:38 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Narrative](#)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User closed query 'PV Query: Did the subject experienced any signs and symptoms for this episode? If yes, then please update the event onset date with the date of first start of signs and symptoms. If No, then please state so.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 18:31:04 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 18:31:01 |
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 16 Feb 2021 18:30:48 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent discharge summary to the safety team via email' (Site from Safety). | (b) (4), (b) (6) | 12 Feb 2021 16:27:15 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Narrative](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------|
| User entered 'SUBJECT HAS MEDICAL HISTORY OF MULTIPLE SMALL BOWEL OBSTRUCTIONS. SUBJECT WENT TO ER ON 10/31/20 WHERE SHE RECEIVED A CT SCAN AND WAS DIAGNOSED WITH A SMALL BOWEL OBSTRUCTION. SUBJECT WENT HOME AND WAS NOT ADMITTED. SUBJECT THEN WENT BACK TO ER THE NEXT DAY ON 11/01/20 AND WAS ADMITTED. SUBJECT RECEIVED NASOGASTRIC TUBE PROCEDURE AND WAS DISCHARGED ON 11/02/20. MEDICAL RECORDS ARE PENDING. -Update 02/12/2021 -Medical records received and reviewed. Subject had dates mixed up so updated dates of hospital stay. Updated associated conmeds and procedures. Verified medications listed per medical records and updated medical history and conmeds.' reason for change: Data Entry Error Query 'PV Query: Did the subject experienced any signs and symptoms for this episode? If yes, then please update the event onset date with the date of first start of signs and symptoms. If No, then please state so.' answered with 'Updated date with onset of symptoms' (Site from Safety). | (b) (4), (b) (6) | 12 Feb 2021 14:59:08 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID testing not done' (Site from Safety). | (b) (4), (b) (6) | 12 Feb 2021 14:57:04 |
| User closed query 'PV Query: As the subject had medical history of multiple small bowel obstructions, kindly add the same in the medical history section of the eCRF.' (Site from Safety). | (b) (4), (b) (6) | 12 Feb 2021 14:55:35 |
| Query 'PV Query: As the subject had medical history of multiple small bowel obstructions, kindly add the same in the medical history section of the eCRF.' answered with 'done' (Site from Safety). | (b) (4), (b) (6) | 03 Feb 2021 16:52:15 |
| Query 'PV Query: As the subject had medical history of multiple small bowel obstructions, kindly add the same in the medical history section of the eCRF.' answered with 'done' (Site from Safety). | Patty Howenstine (b) (4) (b) (4) | 02 Feb 2021 20:09:39 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Narrative](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| User opened query 'PV Query: Did the subject experienced any signs and symptoms for this episode? If yes, then please update the event onset date with the date of first start of signs and symptoms. If No, then please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Jan 2021 16:55:29 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Jan 2021 16:54:57 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 29 Jan 2021 16:54:42 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Jan 2021 16:54:29 |
| User opened query 'PV Query: As the subject had medical history of multiple small bowel obstructions, kindly add the same in the medical history section of the eCRF.' (Site from Safety). | (b) (4), (b) (6) | 29 Jan 2021 16:53:28 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:16:34 |
| User entered 'Subject has medical history of multiple small bowel obstructions. Subject went to ER on 10/31/20 where she received a CT scan and was diagnosed with a small bowel obstruction. Subject went home and was not admitted. Subject then went back to ER the next day on 11/01/20 and was admitted. Subject received nasogastric tube procedure and was discharged on 11/02/20. Medical records are pending.' | (b) (4), (b) (6) | 21 Jan 2021 23:54:45 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Jan 2021 23:54:45 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 21 Jan 2021 23:54:45 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:17:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 21 Jan 2021 23:54:45 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:06:39 |
| User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 11:43:36 |
| Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'Confirmed listed in Medical History' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 19:47:35 |
| User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM). | (b) (4), (b) (6) | 23 Mar 2021 20:02:24 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:41 |
| User entered 'Yes (Y)' reason for change: New Information | (b) (4), (b) (6) | 22 Jan 2021 20:31:14 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:27:54 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User closed query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM). | (b) (4), (b) (6) | 05 Mar 2021 12:45:53 |
| Query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' answered with 'confirm does not meet EC#9' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 18:35:33 |
| User opened query 'Per MM, please confirm if this vaccination meets the EC #9 'Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP, see Section 6.4.3).' and please raise a PD accordingly. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:42:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| 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) | 22 Jan 2021 20:37:11 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Jan 2021 20:37:11 |
| Data point term sent to Coder | System | 22 Jan 2021 20:36:32 |
| User entered 'influenza vaccine' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'influenza prophylaxis' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'l' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'injection' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered empty. | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered empty. | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'un Oct 2020' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered '0' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'un Oct 2020' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:00:59 |
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Jan 2021 20:35:48 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User entered empty. | System | 22 Jan 2021 20:35:48 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User entered empty. | System | 22 Jan 2021 20:35:48 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:41 |
| User entered empty. | System | 22 Jan 2021 20:35:48 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Name of Medication](#)

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL, PRODUCTSYNONYM: ISOVUE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Feb 2021 14:52:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Feb 2021 14:52:48 |
| Data point term sent to Coder | System | 12 Feb 2021 14:52:02 |
| User entered 'isovue' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'recurrent small bowel obstruction' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '90' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'mL (mL)' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '02 Nov 2020' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '02 Nov 2020' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User entered empty. | System | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User entered empty. | System | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:51 |
| User entered empty. | System | 12 Feb 2021 14:51:26 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Feb 2021 12:19:58 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Feb 2021 12:19:58 |
| Data point term sent to Coder | System | 12 Feb 2021 14:52:02 |
| User entered 'morphine' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'recurrent small bowel obstruction' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '4' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Route of administration](#)

| Audit | User | Time (GMT) |
|------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'Intravenous (INTRAVENOUS)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '03 Nov 2020' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '03 Nov 2020' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User entered empty. | System | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User entered empty. | System | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 07:58:58 |
| User entered empty. | System | 12 Feb 2021 14:52:01 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Name of Medication](#)

| Audit | User | Time (GMT) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Feb 2021 14:53:47 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Feb 2021 14:53:47 |
| Data point term sent to Coder | System | 12 Feb 2021 14:53:10 |
| User entered 'clonazepam' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'difficulty sleeping' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '.25' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'un Oct 2020' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:52:46 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Feb 2021 14:52:46 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

Name of Medication

| Audit | User | Time (GMT) |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HCTZ - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 11:36:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Feb 2021 11:36:56 |
| Data point term sent to Coder | System | 12 Feb 2021 14:54:11 |
| User entered 'HCTZ/Triamterene' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'lower extremity edema' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '25/37.5' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'un UNK 2001' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered '0' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |
| | | |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:09:34 |
| User entered 'No (N)' | (b) (4), (b) (6) | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:10

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 12 Feb 2021 14:53:31 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:17:10

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|-----------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:06:39 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 13:55:05 |
| User entered 'Yes (Y)' reason for change: New Information | (b) (4), (b) (6) | 22 Jan 2021 20:28:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 31 Aug 2020 17:28:00 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:10

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 13:58:17 |
| User entered '02 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Feb 2021 14:46:31 |
| User entered '01 Nov 2020' | (b) (4), (b) (6) | 22 Jan 2021 20:28:51 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:10

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 13:58:18 |
| User entered 'nasogastric tube' | (b) (4), (b) (6) | 22 Jan 2021 20:28:51 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 13:58:20 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 22 Jan 2021 20:28:51 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:10

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 13:58:22 |
| User entered empty. | (b) (4), (b) (6) | 22 Jan 2021 20:28:51 |
| | | |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:10

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:32 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 25 Feb 2021 14:07:10 |
| User entered '01 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Feb 2021 14:46:50 |
| User entered '31 Oct 2020' | (b) (4), (b) (6) | 22 Jan 2021 20:30:46 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:10

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-------------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:32 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:07:11 |
| User entered 'CT scan (without contrast)' | (b) (4), (b) (6) | 22 Jan 2021 20:30:46 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:32 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:07:13 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 22 Jan 2021 20:30:46 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:10

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:32 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 14:07:15 |
| User entered empty. | (b) (4), (b) (6) | 22 Jan 2021 20:30:46 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:10

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 13:59:01 |
| User entered '02 Nov 2020' | (b) (4), (b) (6) | 12 Feb 2021 14:47:12 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:10

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|----------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 13:59:04 |
| User entered 'CT scan (with contrast)' | (b) (4), (b) (6) | 12 Feb 2021 14:47:12 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:10

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 13:59:05 |
| User entered 'Adverse Event (AE)' | (b) (4), (b) (6) | 12 Feb 2021 14:47:12 |

US3672388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:10

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 12:12:36 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Feb 2021 13:59:07 |
| User entered empty. | (b) (4), (b) (6) | 12 Feb 2021 14:47:12 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered | | |
| 'USA-US116-2021-MRNA-1273-P301000004' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Cynthia' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Strout' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Street

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '1156 Bowman Road' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '4920 O Hear ave Suite 101' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '1156 Bowman Road' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered 'Mount Pleasant' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered 'North Charleston' reason for change: | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Mount Pleasant' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered empty. | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'SC' | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '29464' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '29405' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '29464' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'US' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 05 Apr 2021 14:51:13 |
| User entered '5' | System | 19 Mar 2021 15:43:20 |
| User entered '4' | System | 04 Mar 2021 13:36:04 |
| User entered '3' | System | 16 Feb 2021 18:33:44 |
| User entered '2' | System | 03 Feb 2021 16:54:30 |
| User entered '1' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered | | |
| 'USA-US116-2021-MRNA-1273-P301000004' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Cynthia' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Strout' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Street

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '1156 Bowman Road' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '4920 O Hear ave Suite 101' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '1156 Bowman Road' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered 'Mount Pleasant' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered 'North Charleston' reason for change: | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Mount Pleasant' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered empty. | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'SC' | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '29464' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '29405' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '29464' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'US' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 05 Apr 2021 14:51:13 |
| User entered '5' | System | 19 Mar 2021 15:43:20 |
| User entered '4' | System | 04 Mar 2021 13:36:04 |
| User entered '3' | System | 16 Feb 2021 18:33:44 |
| User entered '2' | System | 03 Feb 2021 16:54:30 |
| User entered '1' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:17:10

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered '22/Jan/2021 15:16' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:17:10

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. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'I' | (b) (4), (b) (6) | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered | System | 22 Jan 2021 15:16:17 |
| 'USA-US116-2021-MRNA-1273-P301000004' | | |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Cynthia' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Strout' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Street

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '1156 Bowman Road' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '4920 O Hear ave Suite 101' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '1156 Bowman Road' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered 'Mount Pleasant' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered 'North Charleston' reason for change: | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Mount Pleasant' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered empty. | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'SC' | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '29464' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '29405' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '29464' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'US' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 05 Apr 2021 14:51:13 |
| User entered '5' | System | 19 Mar 2021 15:43:20 |
| User entered '4' | System | 04 Mar 2021 13:36:04 |
| User entered '3' | System | 16 Feb 2021 18:33:44 |
| User entered '2' | System | 03 Feb 2021 16:54:30 |
| User entered '1' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:17:10

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '03/Feb/2021 11:54' | (b) (4) System | 03 Feb 2021 16:54:30 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:17:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| User entered 'I' | (b) (4), (b) (6) | 03 Feb 2021 16:54:30 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered | | |
| 'USA-US116-2021-MRNA-1273-P301000004' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Cynthia' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Strout' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Street

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '1156 Bowman Road' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '4920 O Hear ave Suite 101' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '1156 Bowman Road' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered 'Mount Pleasant' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered 'North Charleston' reason for change: | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Mount Pleasant' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered empty. | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'SC' | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '29464' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '29405' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '29464' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'US' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 05 Apr 2021 14:51:13 |
| User entered '5' | System | 19 Mar 2021 15:43:20 |
| User entered '4' | System | 04 Mar 2021 13:36:04 |
| User entered '3' | System | 16 Feb 2021 18:33:44 |
| User entered '2' | System | 03 Feb 2021 16:54:30 |
| User entered '1' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:17:10

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '16/Feb/2021 13:33' | (b) (4) System | 16 Feb 2021 18:33:44 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:17:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 04 Mar 2021 13:35:48 |
| User entered 'I' | (b) (4), (b) (6) | 16 Feb 2021 18:33:44 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered | | |
| 'USA-US116-2021-MRNA-1273-P301000004' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Cynthia' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Strout' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Street

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '1156 Bowman Road' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '4920 O Hear ave Suite 101' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '1156 Bowman Road' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered 'Mount Pleasant' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered 'North Charleston' reason for change: | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Mount Pleasant' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered empty. | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'SC' | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '29464' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '29405' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '29464' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'US' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 05 Apr 2021 14:51:13 |
| User entered '5' | System | 19 Mar 2021 15:43:20 |
| User entered '4' | System | 04 Mar 2021 13:36:04 |
| User entered '3' | System | 16 Feb 2021 18:33:44 |
| User entered '2' | System | 03 Feb 2021 16:54:30 |
| User entered '1' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:17:10

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered '04/Mar/2021 08:36' | (b) (4) System | 04 Mar 2021 13:36:04 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:17:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Apr 2021 14:51:00 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| User entered 'I' | (b) (4), (b) (6) | 04 Mar 2021 13:36:04 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered | | |
| 'USA-US116-2021-MRNA-1273-P301000004' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Cynthia' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Strout' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Street

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '1156 Bowman Road' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '4920 O Hear ave Suite 101' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '1156 Bowman Road' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered 'Mount Pleasant' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered 'North Charleston' reason for change: | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Mount Pleasant' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered empty. | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'SC' | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '29464' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '29405' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '29464' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'US' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 05 Apr 2021 14:51:13 |
| User entered '5' | System | 19 Mar 2021 15:43:20 |
| User entered '4' | System | 04 Mar 2021 13:36:04 |
| User entered '3' | System | 16 Feb 2021 18:33:44 |
| User entered '2' | System | 03 Feb 2021 16:54:30 |
| User entered '1' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:17:10

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered '19/Mar/2021 11:43' | (b) (4) System | 19 Mar 2021 15:43:20 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:17:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Apr 2021 14:51:00 |
| User entered 'I' | (b) (4), (b) (6) | 19 Mar 2021 15:43:20 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[SAEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered | | |
| 'USA-US116-2021-MRNA-1273-P301000004' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Serious

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Yes (Y)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'No (N)' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Cynthia' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Strout' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Street

| Audit | User | Time (GMT) |
|------------------------------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '1156 Bowman Road' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '4920 O Hear ave Suite 101' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '1156 Bowman Road' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered 'Mount Pleasant' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered 'North Charleston' reason for change: | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Data Entry Error | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered 'Mount Pleasant' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: State

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered empty. | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'SC' | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Un-verified. | System | 03 Feb 2021 16:54:30 |
| User entered '29464' | System | 03 Feb 2021 16:54:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| User entered '29405' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Jan 2021 19:40:51 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Jan 2021 15:16:36 |
| User entered '29464' | System | 22 Jan 2021 15:16:17 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Cynthia Strout (b) (4) | 05 Mar 2021 18:33:55 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 16:54:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 17:17:53 |
| User entered 'US' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '6' | System | 05 Apr 2021 14:51:13 |
| User entered '5' | System | 19 Mar 2021 15:43:20 |
| User entered '4' | System | 04 Mar 2021 13:36:04 |
| User entered '3' | System | 16 Feb 2021 18:33:44 |
| User entered '2' | System | 03 Feb 2021 16:54:30 |
| User entered '1' | System | 22 Jan 2021 15:16:43 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:17:10

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered '05/Apr/2021 10:51' | (b) (4) System | 05 Apr 2021 14:51:13 |

US3672388

Folder: SAE USA-US116-2021-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:17:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:12:04 |
| User signature succeeded. | Cynthia Strout (b) (4) | 16 Apr 2021 15:33:34 |
| User entered 'I' | (b) (4), (b) (6) | 05 Apr 2021 14:51:13 |