

US3142243 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:03:32

All time stamps listed in this document are displayed in GMT

US3142243

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

[Participant ID](#)

US3142243

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

US3142243

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 AUG 2020 |
|--------------------------|-------------|

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

| | |
|------------|------|
| Folder OID | SCRN |
|------------|------|

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1966 |
| Age | 54 |
| Age Units | YEARS |
| Age (Derived) | 54 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 21:37:56

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| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 19 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input checked="" type="radio"/> |
| | Amendment 3 <input type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 21:37:56

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 21:37:56

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 21:37:56

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| | |
|---|--|
| Condition | NEARSIGHTED, BILATERAL |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 21:37:56

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| | |
|---|--|
| Condition | FARSIGHTED, BILATERAL |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN UNK 1985 |
| 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 1985 |
| Start Year (derived) | 1985 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 21:37:56

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| | |
|---|--|
| Condition | SCRATCHY/ SORE THROAT |
| Start date (dd MMM yyyy) | UN UNK 2008 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Condition | POST MENOPAUSAL |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 18 Apr 2021 21:37:56

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| | |
|---|--|
| Condition | INSOMNIA |
| Start date (dd MMM yyyy) | UN UNK 1985 |
| 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 1985 |
| Start Year (derived) | 1985 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 21:37:56

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| | |
|---|--|
| Condition | SHINGLES |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| 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 2015 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | JAN 2015 |
| Stop Year (derived) | 2015 |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 16:35 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 16:35 |
| Height (xxx.x) | 68.5 in |
| Weight (xxx.x) | 150.6 lb |
| BMI (xxx.x) | 22.61277 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) 18 Apr 2021 21:37:56

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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) 18 Apr 2021 21:37:55

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Date of assessment (dd MMM yyyy) 19 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2016

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:56

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:56

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 19 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) 18 Apr 2021 21:37:56

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What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 106206

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) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|--------|---------------|
| 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) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|-------------------------------------|--|
| 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) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 16:35 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 16:35 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|-------------------------------------|--|
| 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) | 19 AUG 2020 |
| Time of assessment (00:00-23:59) | 17:38 (24 HR) |
| Vital Signs Date and Time (derived) | 19 AUG 2020 17:38 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 77 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 159 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 101 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

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) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 17:08 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 17:08

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) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 19 AUG 2020 |
| Collection time (00:00-23:59) | 16:47 (24 HR) |
| Collection date and time (derived) | 19 AUG 2020 16:47 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| Collection date (dd MMM yyyy) | | | 19 AUG 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 16:47 | 19 AUG 2020 16:47 |
| Nasopharyngeal Swab 2 | Yes | 16:47 | 19 AUG 2020 16:47 |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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

19 AUG 2020 17:40

PC Open Date & Time

19 AUG 2020 17:28

PC Close Date & Time

19 AUG 2020 19:58

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °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 | 20 AUG 2020 08:48 |
| PC Open Date & Time | 19 AUG 2020 20:53 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

97.8 °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

21 AUG 2020 09:12

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

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

23 AUG 2020 07:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

23 AUG 2020 12:01

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 12:21

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 08:13

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 17:36

PC Open Date & Time

19 AUG 2020 17:28

PC Close Date & Time

19 AUG 2020 19:58

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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

20 AUG 2020 08:50

PC Open Date & Time

19 AUG 2020 20:53

PC Close Date & Time

20 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 09:13

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

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

23 AUG 2020 07:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:01

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

24 AUG 2020 12:21

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

26 AUG 2020 08:14

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 AUG 2020 17:36 |
| PC Open Date & Time | 19 AUG 2020 17:28 |
| PC Close Date & Time | 19 AUG 2020 19:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 08:50 |
| PC Open Date & Time | 19 AUG 2020 20:53 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

49 of 1726

EAB) (1725)

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 09:14 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

51 of 1726

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

Yes ☐

PC Time stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 07:01 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 12:02 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

57 of 1726

EAB) (1725)

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 12:21 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

59 of 1726

EAB) (1725)

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 08:15 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 26 AUG 2020 12:00

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 27 AUG 2020 16:21

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 11

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 ☐

PC Time Stamp 29 AUG 2020 18:02

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:00

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☒

PC Time Stamp

27 AUG 2020 16:22

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

29 AUG 2020 18:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

30 AUG 2020 18:35

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:00

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:00

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

02 SEP 2020 12:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 26 AUG 2020 12:00 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 27 AUG 2020 16:22 |
| PC Open Date & Time | 27 AUG 2020 12:00 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:03:32

| | |
|---|------------------------------|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 28 AUG 2020 12:00 |
| PC Close Date & Time | 29 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 29 AUG 2020 18:02 |
| PC Open Date & Time | 29 AUG 2020 12:00 |
| PC Close Date & Time | 30 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| TIMEPOINT | DAY 12 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 30 AUG 2020 18:35 |
| PC Open Date & Time | 30 AUG 2020 12:00 |
| PC Close Date & Time | 31 AUG 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| TIMEPOINT | DAY 13 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 31 AUG 2020 12:00 |
| PC Open Date & Time | 31 AUG 2020 12:00 |
| PC Close Date & Time | 01 SEP 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| TIMEPOINT | DAY 14 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 01 SEP 2020 12:00 |
| PC Open Date & Time | 01 SEP 2020 12:00 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 15

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

No ☒

Yes ☐

PC Time stamp

02 SEP 2020 12:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 8

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 26 AUG 2020 12:01

PC Open Date and Time 26 AUG 2020 12:00

PC Close Date and Time 27 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 9

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 27 AUG 2020 16:22

PC Open Date and Time 27 AUG 2020 12:00

PC Close Date and Time 28 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 10

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date and Time

28 AUG 2020 12:00

PC Close Date and Time

29 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 11

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 AUG 2020 18:02

PC Open Date and Time 29 AUG 2020 12:00

PC Close Date and Time 30 AUG 2020 11:59

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 12

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 AUG 2020 18:35

PC Open Date and Time 30 AUG 2020 12:00

PC Close Date and Time 31 AUG 2020 11:59

US3142243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142243

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142243

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 16 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 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|-------------------------------------|---|
| 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) | 16 SEP 2020 |
| Time of assessment (00:00-23:59) | 16:49 (24 HR) |
| Vital Signs Date and Time (derived) | 16 SEP 2020 16:49 |
| Temperature (xxx.x) | 98.0 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 82 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 133 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 93 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

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

SUBJECT HAS MULTIPLE REACTIONS TO FIRST DOSE. SUBJECT DECLINED SECOND BLINDED VACCINE/PLACEBO AND PI AGREED. SITE TO ADD AES TO EDC PER SOURCE.

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3142243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

17:00 (24 HR)

Collection date and time (derived)

16 SEP 2020 17:00

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 9 NOV 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 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|-------------------------------------|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 9 NOV 2020 |
| Time of assessment (00:00-23:59) | 16:41 (24 HR) |
| Vital Signs Date and Time (derived) | 9 NOV 2020 16:41 |
| Temperature (xxx.x) | 98.4 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 10 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 162 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 103 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 NOV 2020

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

US3142243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 9 NOV 2020 |
| Collection time (00:00-23:59) | 16:52 (24 HR) |
| Collection date and time (derived) | 9 NOV 2020 16:52 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 | 22 OCT 2020 07:05:27 |
| Patient Cloud Open Date & Time | 19 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 23 OCT 2020 23:59 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 OCT 2020 18:03:51

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

06 NOV 2020 18:04:46

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 92 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="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"/> |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 | 23 NOV 2020 18:35:01 |
| Patient Cloud Open Date & Time | 20 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 24 NOV 2020 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

28 NOV 2020 13:32:12

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 110 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 06 DEC 2020 12:01:05 |
| Patient Cloud Open Date & Time | 04 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 08 DEC 2020 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 10:11:55

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 20 DEC 2020 12:00:53 |
| Patient Cloud Open Date & Time | 18 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 22 DEC 2020 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 05:34:07

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

01 JAN 2021 19:30:53

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

11 JAN 2021 20:49:12

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

16 JAN 2021 12:54:00

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 05:49:27

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 15:32:41

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

07 FEB 2021 13:38:11

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

12 FEB 2021 17:20:32

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

19 FEB 2021 07:49:05

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 18:49:19

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 MAR 2021 20:49:25 |
| Patient Cloud Open Date & Time | 05 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 09 MAR 2021 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

12 MAR 2021 17:35:43

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

21 MAR 2021 19:34:00

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

26 MAR 2021 16:28:27

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

04 APR 2021 09:29:41

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| 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 | 10 APR 2021 12:15:13 |
| Patient Cloud Open Date & Time | 09 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 13 APR 2021 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

19 APR 2021 20:13:23

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 12:21:47

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 278 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 292 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 20 JUL 2021 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 355 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 369 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 <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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 14 SEP 2021 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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°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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 446 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 453 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 16 NOV 2021 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 14 DEC 2021 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 488 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 21 DEC 2021 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 502 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 <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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 <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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 544 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 <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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 <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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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 <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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 05 APR 2022 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 642 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

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24 MAY 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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31 MAY 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

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03 JUN 2022 00:01

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07 JUN 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 663 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 | 17 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 21 JUN 2022 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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 ☐

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

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 | 15 JUL 2022 00:01 |
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US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 JUL 2022 00:01 |
| Patient Cloud Close Date & Time | 26 JUL 2022 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 712 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 747 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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06 SEP 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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20 SEP 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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="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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| TIMEPOINT | DAY 782 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 07 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 11 OCT 2022 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 14 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 18 OCT 2022 23:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

| 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"/> |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3142243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:03:32

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 27 FEB 2021 18:49:30 |

US3142243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142243

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3142243

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142243

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142243

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT4

US3142243

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 21:37:56

Generated On: 11 Aug 2021 22:03:32

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3142243

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:03:32

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3142243

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

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3142243

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

Form: Unblinding

Generated On: 11 Aug 2021 22:03:32

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

US3142243

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

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

| | |
|--|-------|
| Collection date (<i>dd MMM yyyy</i>) | _____ |
| Collection time (<i>00:00-23:59</i>) | _____ |
| Collection date and time (derived) | _____ |

US3142243

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:03:32

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00 - 23:59*)

Collection Date and Time (derived)

US3142243

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

| | |
|--|--|
| AEID | |
| Adverse event | FATIGUE |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input checked="" type="radio"/> No <input 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) | 26 AUG 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) | 07 SEP 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input 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 | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input 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 checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

AEID

Adverse event

SITE INJECTION PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

AEID

Adverse event

LEFT ARMPIT SWELLING

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

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

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

AEID

Adverse event

MENTAL FOGGINESS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

29 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 18 Apr 2021 21:37:53

Generated On: 11 Aug 2021 22:03:32

| | |
|--|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input 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 checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| <hr/> | |
| Narrative | |
| <hr/> | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

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

Yes ☒

No ☐

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

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

Name of Medication PROGESTERONE

Prophylaxis Yes ☐
No ☒

Indication MENOPAUSAL

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication MENOPAUSAL

Dose per administration 1

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2019 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

| | | |
|--|--------------------------|----------------------------------|
| | 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 2015 | |
| 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"/> |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

Name of Medication XANAX

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

| | | |
|--|--------------------------------------|-------------------------------------|
| | 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 1985 |
| 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 checked="" type="radio"/> | 803 <input type="radio"/> |
| | 804 <input type="radio"/> | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

Name of Medication XYZAL

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 21:37:54

Generated On: 11 Aug 2021 22:03:32

| | | |
|--|--------------------------|----------------------------------|
| | 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 2013 | |
| 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"/> |

US3142243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3142243

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 18 Apr 2021 21:37:55

Generated On: 11 Aug 2021 22:03:32

Date of dosing discontinuation (dd MMM yyyy) 19 AUG 2020

Primary reason for dosing discontinuation

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

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

| |
|---------------------------|
| LEFT ARMPIT SWELLING AE#3 |
| FATIGUE AE#1 |
| SITE INJECTION PAIN #3 |

US3142243

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:03:32

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3142243 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142243

Form: Participant Creation

Generated On: 11 Aug 2021 22:03:32

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'US3142243' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 22:19:27 |

US3142243

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:07 |

US3142243

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 22:19:28 |

US3142243

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Clinic (Clinic)' | Meghan York (b) (4) | 04 Sep 2020 15:46:07 |

US3142243

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'SCRN' | System | 04 Sep 2020 15:46:07 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per CDM : Please complete this form' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 04:05:13 |
| Query 'Per CDM : Please complete this form' answered with 'data is complete' (Site from DM). | Jami Wagner (b) (4) | 07 Oct 2020 16:40:11 |
| User opened query 'Per CDM : Please complete this form' (Site from DM). | (b) (4) (b) (4), (b) (6) | 27 Aug 2020 15:08:39 |
| User entered '(b) (6)1966' | RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 22:19:29 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '54' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'YEARS' | System | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '54' | System | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Female (F)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

White

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'I' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:32

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:46:31 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | Meghan York (b) (4) | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Aug 2020' | System | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '2020' | System | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

[Protocol Version](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Amendment 2 (2)' reason for change: | (b) (4) | |
| Data Entry Error | Meghan York (b) (4) | 09 Dec 2020 23:45:20 |
| User entered 'Amendment 1 (1)' | (b) (4) | |
| | Meghan York (b) (4) | 19 Aug 2020 23:30:02 |
| | (b) (4) | |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:02 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 22:19:28 |

US3142243

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:03:32

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '1' | System | 19 Aug 2020 23:30:05 |

US3142243

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:05 |

US3142243

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:03:32

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:46:40 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Please update the condition to include the laterality of NEARSIGHTEDNESS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4) (b) (4), (b) (6) | 23 Oct 2020 16:02:30 |
| ' (Site from DM). | | |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Oct 2020 20:33:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Oct 2020 20:33:28 |
| Data point term sent to Coder | System | 19 Oct 2020 20:32:13 |
| Query 'Per DM CLR: Please update the condition to include the laterality of NEARSIGHTEDNESS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:31:30 |
| ' answered with 'done' (Site from DM). | | |
| Coding entries removed. | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:31:25 |
| User entered 'NEARSIGHTED, bilateral' reason for change: Data Entry Error | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:31:25 |
| User opened query 'Per DM CLR: Please update the condition to include the laterality of NEARSIGHTEDNESS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 30 Sep 2020 06:04:19 |
| ' (Site from DM). | | |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 15:48:38 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 04 Sep 2020 15:48:38 |
| User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 04 Sep 2020 15:48:12 |
| User entered 'nearsighted' | Meghan York (b) (4) | 04 Sep 2020 15:47:21 |
| | (b) (4) | |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2018' | Meghan York (b) (4) | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 2018' | System | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '2018' | System | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:47:21 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Please update the condition to include the laterality of FARSIGHTEDNESS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4) | 23 Oct 2020 16:02:37 |
| ' (Site from DM). | (b) (4), (b) (6) | |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\23.0. | Coder Import (b) (4) | 19 Oct 2020 20:32:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | (b) (4) | 19 Oct 2020 20:32:26 |
| Data point term sent to Coder | System | 19 Oct 2020 20:32:13 |
| Query 'Per DM CLR: Please update the condition to include the laterality of FARSIGHTEDNESS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | Meghan York (b) (4) | 19 Oct 2020 20:31:43 |
| ' answered with 'done' (Site from DM). | (b) (4) | |
| Coding entries removed. | Meghan York (b) (4) | 19 Oct 2020 20:31:38 |
| User entered 'FARSIGHTED, bilateral' reason for change: Data Entry Error | (b) (4) | 19 Oct 2020 20:31:38 |
| User opened query 'Per DM CLR: Please update the condition to include the laterality of FARSIGHTEDNESS (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6) | 30 Sep 2020 06:04:28 |
| ' (Site from DM). | | |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Farsighted - version MedDRA\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:48:38 |
| | (b) (4) | |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 04 Sep 2020 15:48:38 |
| User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 04 Sep 2020 15:48:12 |
| User entered 'farsighted' | Meghan York (b) (4) | 04 Sep 2020 15:47:42 |
| | (b) (4) | |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2018' | Meghan York (b) (4) | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 2018' | System | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '2018' | System | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:47:42 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:49:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:49:43 |
| Data point term sent to Coder | System | 04 Sep 2020 15:49:15 |
| User entered 'seasonal allergies' | Meghan York (b) (4) | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 1985' | Meghan York (b) (4) | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 1985' | System | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '1985' | System | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:48:18 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Sep 2020 12:20:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Sep 2020 12:20:47 |
| Data point term sent to Coder | System | 04 Sep 2020 15:54:27 |
| User entered 'scratchy/ sore throat' | Meghan York (b) (4) | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2008' | Meghan York (b) (4) | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 2008' | System | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '2008' | System | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:54:03 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:56:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:56:42 |
| Data point term sent to Coder | System | 04 Sep 2020 15:55:28 |
| User entered 'post menopausal' | Meghan York (b) (4) | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2016' | Meghan York (b) (4) | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 2016' | System | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '2016' | System | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:54:31 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:56:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:56:42 |
| Data point term sent to Coder | System | 04 Sep 2020 15:55:29 |
| User entered 'insomnia' | Meghan York (b) (4) | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 1985' reason for change: | (b) (4) | |
| Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:30:47 |
| User entered 'UN UNK 2015' | (b) (4) | |
| | Meghan York (b) (4) | 04 Sep 2020 15:55:01 |
| | (b) (4) | |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 1985' | System | 19 Oct 2020 20:30:47 |
| User entered 'Jan 2015' | System | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '1985' | System | 19 Oct 2020 20:30:47 |
| User entered '2015' | System | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered empty. | System | 04 Sep 2020 15:55:01 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:57:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 04 Sep 2020 15:57:42 |
| Data point term sent to Coder | System | 04 Sep 2020 15:56:30 |
| User entered 'shingles' | Meghan York (b) (4) | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2015' | Meghan York (b) (4) | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2015' | Meghan York (b) (4) | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 2015' | System | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '2015' | System | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'Jan 2015' | System | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '2015' | System | 04 Sep 2020 15:55:34 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:35' | Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '19 Aug 2020 16:35' | System | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '68.5' in | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |
| DataPoint set to visible. | (b) (4) System | 19 Aug 2020 23:30:05 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '150.6' lb | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |
| DataPoint set to visible. | (b) (4) System | 19 Aug 2020 23:30:05 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered '22.61277' | System | 04 Sep 2020 15:57:02 |
| DataPoint set to visible. | System | 19 Aug 2020 23:30:05 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'kg/m2' | System | 04 Sep 2020 15:57:02 |
| DataPoint set to visible. | System | 19 Aug 2020 23:30:05 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'bpm' | System | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'breaths/min' | System | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'mmHg' | System | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User entered 'mmHg' | System | 04 Sep 2020 15:57:02 |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| | | |

US3142243

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| | | |

US3142243

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:57:20 |

US3142243

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | Meghan York (b) (4) | 04 Sep 2020 15:57:20 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

[If No, what is the reason?](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | (b) (4) Meghan York (b) (4) (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

[If Partner medically sterile or Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2016' reason for change: Data Entry Error | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:26 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 04 Sep 2020 15:58:12 |
| User entered 'UN UNK 2020' reason for change: Data Entry Error | Meghan York (b) (4) (b) (4) | 04 Sep 2020 15:58:12 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 04 Sep 2020 15:58:02 |
| User entered 'uk UNK 2016' (non-conformant). | Meghan York (b) (4) (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:32

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 15:58:02 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

[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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

[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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

[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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

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 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'I' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

Other

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:32

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:19:00 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:58:54 |

US3142243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 27 Aug 2020 23:59:46 |

US3142243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | Jill York (b) (4) | 27 Aug 2020 23:59:46 |

US3142243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Clinic (Clinic)' | Jill York (b) (4) | 27 Aug 2020 23:59:46 |

US3142243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'VISIT1' | System | 27 Aug 2020 23:59:46 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 23:09:10 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 05:44:43 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:44:42 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 19 Aug 2020 23:09:10 |
| User entered '106206' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 23:09:10 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 19 Aug 2020 23:09:10 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

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) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Oct 2020 18:43:32 |
| Query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' answered with 'form is now complete ' (Site from DM). | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:32:04 |
| User entered 'No (N)' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 15:59:10 |
| User opened query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM). | (b) (4), (b) (6) | 31 Aug 2020 13:46:44 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

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) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:59:10 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:59:10 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:59:10 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 15:59:10 |

US3142243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:32

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| DataPoint set to visible. | System | 09 Dec 2020 23:45:20 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:39:06 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:32

Height

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:32

Weight

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:32

Height

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:32

Weight

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:35' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '19 Aug 2020 16:35' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '98.3' F | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Other (Other)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'temporal' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '80' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'bpm' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '14' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'breaths/min' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '118' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'mmHg' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '78' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'mmHg' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:32

[Height](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:32

Weight

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered missing code ND - Not Done. | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '17:38' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '19 Aug 2020 17:38' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '98.5' F | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Other (Other)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'temporal' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '77' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'bpm' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '14' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'breaths/min' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) System | 17 Sep 2020 00:15:13 |
| Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 17 Sep 2020 00:15:13 |
| Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." | System | 17 Sep 2020 00:15:13 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 04 Sep 2020 16:02:01 |
| User entered '159' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'mmHg' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) (b) (4) | 18 Apr 2021 21:37:57 |
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 17 Sep 2020 00:15:13 |
| User opened query 'Diastolic Blood Pressure reportedSystem is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 04 Sep 2020 16:02:01 |
| User entered '101' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'mmHg' | System | 04 Sep 2020 16:02:01 |

US3142243

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 29 Sep 2020 15:18:54 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Meghan York (b) (4) | 04 Sep 2020 16:02:25 |
| | (b) (4) | |

US3142243

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 29 Sep 2020 15:18:54 |
| User entered '19 Aug 2020' | (b) (4) | |
| | Meghan York (b) (4) | 04 Sep 2020 16:02:25 |
| | (b) (4) | |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

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) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) (b) (4) | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '17:08' | (b) (4) Meghan York (b) (4) | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '19 Aug 2020 17:08' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Left Arm (LEFT ARM)' | Meghan York (b) (4) | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'ONCE' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'INTRAMUSCULAR' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:54 |

US3142243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | Meghan York (b) (4) | 04 Sep 2020 16:02:54 |

US3142243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:47' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:02:54 |

US3142243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '19 Aug 2020 16:47' | System | 04 Sep 2020 16:02:54 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:03:32

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | Meghan York (b) (4) | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:47' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '19 Aug 2020 16:47' | System | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:47' | Meghan York (b) (4) | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '19 Aug 2020 16:47' | System | 04 Sep 2020 16:03:32 |

US3142243

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 28 Aug 2020 00:01:08 |

US3142243

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '1' | System | 28 Aug 2020 00:01:08 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:39:52', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '44c8b05c-f17b-42d0-ac56-ff09fec600b2' User entered 'Yes (Y)' | System | 19 Aug 2020 23:40:12 |
| | System | 19 Aug 2020 23:40:12 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:40:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '44c8b05c-f17b-42d0-ac56-ff09fec600b2' User entered '98.5' | System | 19 Aug 2020 23:40:12 |
| | System | 19 Aug 2020 23:40:12 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:40:05', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '44c8b05c-f17b-42d0-ac56-ff09fec600b2' | System | 19 Aug 2020 23:40:12 |
| User entered 'No (N)' | System | 19 Aug 2020 23:40:12 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:40:09', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '44c8b05c-f17b-42d0-ac56-ff09fec600b2' | System | 19 Aug 2020 23:40:12 |
| User entered '19 Aug 2020 17:40' | System | 19 Aug 2020 23:40:12 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 17:28' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 19:58' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:48:31', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '7197d544-1ad3-4aad-a656-f5d32251fd2d' User entered 'Yes (Y)' | System | 20 Aug 2020 14:48:57 |
| | System | 20 Aug 2020 14:48:57 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:48:42', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '7197d544-1ad3-4aad-a656-f5d32251fd2d' User entered '98.0' | System | 20 Aug 2020 14:48:57 |
| | System | 20 Aug 2020 14:48:57 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:48:49', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '7197d544-1ad3-4aad-a656-f5d32251fd2d' User entered 'No (N)' | System | 20 Aug 2020 14:48:57 |
| | System | 20 Aug 2020 14:48:57 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:48:55', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '7197d544-1ad3-4aad-a656-f5d32251fd2d' User entered '20 Aug 2020 08:48' | System | 20 Aug 2020 14:48:57 |
| | System | 20 Aug 2020 14:48:57 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 20:53' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 2' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:12:02', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0e2208e3-2c9d-49ef-8004-ba795d7fd54f' User entered 'Yes (Y)' | System | 21 Aug 2020 15:12:29 |
| | System | 21 Aug 2020 15:12:29 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:12:13', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0e2208e3-2c9d-49ef-8004-ba795d7fd54f' User entered '97.8' | System | 21 Aug 2020 15:12:29 |
| | System | 21 Aug 2020 15:12:29 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:12:21', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0e2208e3-2c9d-49ef-8004-ba795d7fd54f' User entered 'No (N)' | System | 21 Aug 2020 15:12:29 |
| | System | 21 Aug 2020 15:12:29 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:12:27', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0e2208e3-2c9d-49ef-8004-ba795d7fd54f' User entered '21 Aug 2020 09:12' | System | 21 Aug 2020 15:12:29 |
| | System | 21 Aug 2020 15:12:29 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 3' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| | | |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| | | |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 4' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:00:56', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '88f2d29e-68dc-4f38-ac61-3f191bac854c' User entered 'Yes (Y)' | System | 23 Aug 2020 13:01:14 |
| | System | 23 Aug 2020 13:01:14 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:02', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '88f2d29e-68dc-4f38-ac61-3f191bac854c' User entered '98.2' | System | 23 Aug 2020 13:01:14 |
| | System | 23 Aug 2020 13:01:14 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:08', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '88f2d29e-68dc-4f38-ac61-3f191bac854c' User entered 'No (N)' | System | 23 Aug 2020 13:01:14 |
| | System | 23 Aug 2020 13:01:14 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:12', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '88f2d29e-68dc-4f38-ac61-3f191bac854c' User entered '23 Aug 2020 07:01' | System | 23 Aug 2020 13:01:14 |
| | System | 23 Aug 2020 13:01:14 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 5' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:00:51', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '54d00161-b577-4aaa-a477-f17b911f7a47' | System | 23 Aug 2020 18:01:16 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 18:01:16 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:02', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '54d00161-b577-4aaa-a477-f17b911f7a47' User entered '98.0' | System | 23 Aug 2020 18:01:16 |
| | System | 23 Aug 2020 18:01:16 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:06', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '54d00161-b577-4aaa-a477-f17b911f7a47' | System | 23 Aug 2020 18:01:16 |
| User entered 'No (N)' | System | 23 Aug 2020 18:01:16 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:14', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '54d00161-b577-4aaa-a477-f17b911f7a47' | System | 23 Aug 2020 18:01:16 |
| User entered '23 Aug 2020 12:01' | System | 23 Aug 2020 18:01:16 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 6' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:20:42', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '4b4ae029-6f09-4ab7-a011-19e6166be320' User entered 'Yes (Y)' | System | 24 Aug 2020 18:21:06 |
| | System | 24 Aug 2020 18:21:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:20:55', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '4b4ae029-6f09-4ab7-a011-19e6166be320' User entered '98.7' | System | 24 Aug 2020 18:21:06 |
| | System | 24 Aug 2020 18:21:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:20:59', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '4b4ae029-6f09-4ab7-a011-19e6166be320' | System | 24 Aug 2020 18:21:06 |
| User entered 'No (N)' | System | 24 Aug 2020 18:21:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:04', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '4b4ae029-6f09-4ab7-a011-19e6166be320' User entered '24 Aug 2020 12:21' | System | 24 Aug 2020 18:21:06 |
| | System | 24 Aug 2020 18:21:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 7' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:13:45', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd5f936e0-1294-4be0-8e36-fd8306962d4d' User entered 'Yes (Y)' | System | 26 Aug 2020 14:14:01 |
| | System | 26 Aug 2020 14:14:01 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:13:50', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd5f936e0-1294-4be0-8e36-fd8306962d4d' User entered '98.7' | System | 26 Aug 2020 14:14:01 |
| | System | 26 Aug 2020 14:14:01 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:13:55', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd5f936e0-1294-4be0-8e36-fd8306962d4d' User entered 'No (N)' | System | 26 Aug 2020 14:14:01 |
| | System | 26 Aug 2020 14:14:01 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:13:59', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd5f936e0-1294-4be0-8e36-fd8306962d4d' User entered '26 Aug 2020 08:13' | System | 26 Aug 2020 14:14:01 |
| | System | 26 Aug 2020 14:14:01 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:35:23', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '89080add-09ac-450c-9b04-a9b9e728f76f' User entered 'None (1)' | System | 19 Aug 2020 23:36:08 |
| | System | 19 Aug 2020 23:36:08 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:35:29', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '89080add-09ac-450c-9b04-a9b9e728f76f' User entered 'No (N)' | System | 19 Aug 2020 23:36:08 |
| | System | 19 Aug 2020 23:36:08 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:35:39', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '89080add-09ac-450c-9b04-a9b9e728f76f' User entered 'No (N)' | System | 19 Aug 2020 23:36:08 |
| | System | 19 Aug 2020 23:36:08 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:35:45', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '89080add-09ac-450c-9b04-a9b9e728f76f' User entered 'None (1)' | System | 19 Aug 2020 23:36:08 |
| | System | 19 Aug 2020 23:36:08 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:03', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '89080add-09ac-450c-9b04-a9b9e728f76f' User entered '19 Aug 2020 17:36' | System | 19 Aug 2020 23:36:08 |
| | System | 19 Aug 2020 23:36:08 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 17:28' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 19:58' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:49:25', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ee3ce75c-f2ba-4619-ba9a-7adcdb8f0a2f' User entered 'Does not interfere with activity (2)' | System | 20 Aug 2020 14:50:04 |
| | | |
| | System | 20 Aug 2020 14:50:04 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:49:39', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ee3ce75c-f2ba-4619-ba9a-7adcdb8f0a2f' User entered 'No (N)' | System | 20 Aug 2020 14:50:04 |
| | System | 20 Aug 2020 14:50:04 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:49:43', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ee3ce75c-f2ba-4619-ba9a-7adcd8f0a2f' User entered 'No (N)' | System | 20 Aug 2020 14:50:04 |
| | System | 20 Aug 2020 14:50:04 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:49:56', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ee3ce75c-f2ba-4619-ba9a-7adcdb8f0a2f' User entered 'None (1)' | System | 20 Aug 2020 14:50:04 |
| | System | 20 Aug 2020 14:50:04 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ee3ce75c-f2ba-4619-ba9a-7adcd8f0a2f' User entered '20 Aug 2020 08:50' | System | 20 Aug 2020 14:50:04 |
| | System | 20 Aug 2020 14:50:04 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 20:53' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 2' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:12:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '41b296b8-a7ce-4980-9f88-c14e85593972' | System | 21 Aug 2020 15:13:33 |
| User entered 'Does not interfere with activity (2)' | System | 21 Aug 2020 15:13:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:12:43', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '41b296b8-a7ce-4980-9f88-c14e85593972' User entered 'No (N)' | System | 21 Aug 2020 15:13:33 |
| | System | 21 Aug 2020 15:13:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:12:57', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '41b296b8-a7ce-4980-9f88-c14e85593972' | System | 21 Aug 2020 15:13:33 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 15:13:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:17', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '41b296b8-a7ce-4980-9f88-c14e85593972' User entered '1' | System | 21 Aug 2020 15:13:33 |
| | System | 21 Aug 2020 15:13:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:25', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '41b296b8-a7ce-4980-9f88-c14e85593972' User entered 'None (1)' | System | 21 Aug 2020 15:13:33 |
| | System | 21 Aug 2020 15:13:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:30', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '41b296b8-a7ce-4980-9f88-c14e85593972' User entered '21 Aug 2020 09:13' | System | 21 Aug 2020 15:13:33 |
| | System | 21 Aug 2020 15:13:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 3' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| | | |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 4' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:56', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9ab9dd20-ee05-48a4-81e7-9cc1b09e2ec1' User entered 'Does not interfere with activity (2)' | System | 23 Aug 2020 13:02:11 |
| | System | 23 Aug 2020 13:02:11 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:59', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9ab9dd20-ee05-48a4-81e7-9cc1b09e2ec1' User entered 'No (N)' | System | 23 Aug 2020 13:02:11 |
| | System | 23 Aug 2020 13:02:11 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:02:02', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9ab9dd20-ee05-48a4-81e7-9cc1b09e2ec1' User entered 'No (N)' | System | 23 Aug 2020 13:02:11 |
| | System | 23 Aug 2020 13:02:11 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:02:06', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9ab9dd20-ee05-48a4-81e7-9cc1b09e2ec1' User entered 'None (1)' | System | 23 Aug 2020 13:02:11 |
| | System | 23 Aug 2020 13:02:11 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:02:09', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9ab9dd20-ee05-48a4-81e7-9cc1b09e2ec1' User entered '23 Aug 2020 07:02' | System | 23 Aug 2020 13:02:11 |
| | System | 23 Aug 2020 13:02:11 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 5' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:20', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'c8c0be79-2321-45c9-b14c-62b2ab77e61d' User entered 'None (1)' | System | 23 Aug 2020 18:01:43 |
| | System | 23 Aug 2020 18:01:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:23', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'c8c0be79-2321-45c9-b14c-62b2ab77e61d' User entered 'No (N)' | System | 23 Aug 2020 18:01:43 |
| | System | 23 Aug 2020 18:01:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:29', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'c8c0be79-2321-45c9-b14c-62b2ab77e61d' User entered 'No (N)' | System | 23 Aug 2020 18:01:43 |
| | System | 23 Aug 2020 18:01:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'c8c0be79-2321-45c9-b14c-62b2ab77e61d' User entered 'None (1)' | System | 23 Aug 2020 18:01:43 |
| | System | 23 Aug 2020 18:01:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:39', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'c8c0be79-2321-45c9-b14c-62b2ab77e61d' User entered '23 Aug 2020 12:01' | System | 23 Aug 2020 18:01:43 |
| | System | 23 Aug 2020 18:01:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 6' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:10', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e3089e45-1ff6-48fe-9de6-7df20fecbb99' | System | 24 Aug 2020 18:21:31 |
| User entered 'None (1)' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:13', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e3089e45-1ff6-48fe-9de6-7df20fecbb99' | System | 24 Aug 2020 18:21:31 |
| User entered 'No (N)' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:16', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e3089e45-1ff6-48fe-9de6-7df20fecbb99' | System | 24 Aug 2020 18:21:31 |
| User entered 'No (N)' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:24', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e3089e45-1ff6-48fe-9de6-7df20fecbb99' | System | 24 Aug 2020 18:21:31 |
| User entered 'Does not interfere with activity (2)' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:27', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e3089e45-1ff6-48fe-9de6-7df20fecbb99' User entered '24 Aug 2020 12:21' | System | 24 Aug 2020 18:21:31 |
| | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 7' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:09', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'cce3f6e4-443e-4572-ad3b-b6094ddde2a9' | System | 26 Aug 2020 14:14:38 |
| User entered 'Does not interfere with activity (2)' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:13', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'cce3f6e4-443e-4572-ad3b-b6094ddde2a9' User entered 'No (N)' | System | 26 Aug 2020 14:14:38 |
| | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:17', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'cce3f6e4-443e-4572-ad3b-b6094ddde2a9' User entered 'No (N)' | System | 26 Aug 2020 14:14:38 |
| | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:31', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'cce3f6e4-443e-4572-ad3b-b6094ddde2a9' | System | 26 Aug 2020 14:14:38 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'cce3f6e4-443e-4572-ad3b-b6094ddde2a9' User entered '26 Aug 2020 08:14' | System | 26 Aug 2020 14:14:38 |
| | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:10', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered 'None (0)' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:14', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered 'None (0)' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:19', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered 'None (0)' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:25', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered 'None (0)' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:28', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered 'None (0)' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:31', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered 'None (0)' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:41', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered 'No (N)' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-19T17:36:47', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '78e72a2d-03c1-4414-a706-33f7ac6ddc80' User entered '19 Aug 2020 17:36' | System | 19 Aug 2020 23:36:49 |
| | System | 19 Aug 2020 23:36:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 17:28' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 19:58' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:06', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered 'None (0)' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:35', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered 'Some interference with activity (2)' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:39', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered 'None (0)' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:43', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered 'None (0)' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:46', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered 'None (0)' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:49', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered 'None (0)' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:54', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered 'No (N)' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-20T08:50:57', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '185e67ac-bcbd-4177-92f5-3f552d087df0' User entered '20 Aug 2020 08:50' | System | 20 Aug 2020 14:51:09 |
| | System | 20 Aug 2020 14:51:09 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '19 Aug 2020 20:53' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '20 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 2' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' User entered 'None (0)' | System | 21 Aug 2020 15:14:06 |
| | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:41', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' | System | 21 Aug 2020 15:14:06 |
| User entered 'No interference with activity (1)' | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:46', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' User entered 'None (0)' | System | 21 Aug 2020 15:14:06 |
| | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:50', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' User entered 'None (0)' | System | 21 Aug 2020 15:14:06 |
| | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:54', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' User entered 'None (0)' | System | 21 Aug 2020 15:14:06 |
| | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:13:57', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' User entered 'None (0)' | System | 21 Aug 2020 15:14:06 |
| | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:14:01', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' User entered 'No (N)' | System | 21 Aug 2020 15:14:06 |
| | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-21T09:14:04', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6f78efb6-833c-4d60-96e3-230a9502f8b7' User entered '21 Aug 2020 09:14' | System | 21 Aug 2020 15:14:06 |
| | System | 21 Aug 2020 15:14:06 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 3' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| | | |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| | | |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| | | |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| | | |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 4' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:22', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' | System | 23 Aug 2020 13:01:52 |
| User entered 'No interference with activity (1)' | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:26', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' User entered 'None (0)' | System | 23 Aug 2020 13:01:52 |
| | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:31', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' User entered 'None (0)' | System | 23 Aug 2020 13:01:52 |
| | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' User entered 'None (0)' | System | 23 Aug 2020 13:01:52 |
| | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:40', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' User entered 'None (0)' | System | 23 Aug 2020 13:01:52 |
| | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:43', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' User entered 'None (0)' | System | 23 Aug 2020 13:01:52 |
| | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:45', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' User entered 'No (N)' | System | 23 Aug 2020 13:01:52 |
| | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T07:01:48', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb3b7126-723c-4ce1-9a15-d6439db700b5' User entered '23 Aug 2020 07:01' | System | 23 Aug 2020 13:01:52 |
| | System | 23 Aug 2020 13:01:52 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '22 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '23 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 5' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:45', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' User entered 'None (0)' | System | 23 Aug 2020 18:02:23 |
| | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:01:57', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' | System | 23 Aug 2020 18:02:23 |
| User entered 'No interference with activity (1)' | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:02:05', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' User entered 'None (0)' | System | 23 Aug 2020 18:02:23 |
| | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:02:08', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' User entered 'None (0)' | System | 23 Aug 2020 18:02:23 |
| | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:02:11', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' User entered 'None (0)' | System | 23 Aug 2020 18:02:23 |
| | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:02:13', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' User entered 'None (0)' | System | 23 Aug 2020 18:02:23 |
| | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:02:18', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' User entered 'No (N)' | System | 23 Aug 2020 18:02:23 |
| | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-23T12:02:21', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '02e5aa22-2d26-4932-85d2-db2b24a744ae' User entered '23 Aug 2020 12:02' | System | 23 Aug 2020 18:02:23 |
| | System | 23 Aug 2020 18:02:23 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '23 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '24 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 6' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:33', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered 'None (0)' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered 'None (0)' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:39', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered 'None (0)' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:42', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered 'None (0)' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:45', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered 'None (0)' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:48', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered 'None (0)' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:54', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered 'No (N)' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-24T12:21:56', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e4e1c7a7-e662-4a28-af8b-48fa8f4da7fe' User entered '24 Aug 2020 12:21' | System | 24 Aug 2020 18:21:59 |
| | System | 24 Aug 2020 18:21:59 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '24 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '25 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 7' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:43', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered 'None (0)' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:50', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered 'Some interference with activity (2)' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:14:59', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered 'None (0)' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:15:03', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered 'None (0)' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:15:07', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered 'None (0)' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:15:10', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered 'None (0)' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:15:13', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered 'No (N)' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T08:15:16', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '2d3fefd1-dcb5-48d3-a3f3-674f546be8be' User entered '26 Aug 2020 08:15' | System | 26 Aug 2020 14:15:21 |
| | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '25 Aug 2020 12:00' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '26 Aug 2020 11:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 14:14:38 |
| User entered 'Day 8' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:00:46', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '001ffeb2-6389-4701-9ea2-81d64b16f58c' | System | 26 Aug 2020 18:01:20 |
| User entered 'Does not interfere with activity (2)' | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:00:49', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '001ffeb2-6389-4701-9ea2-81d64b16f58c' User entered '26 Aug 2020 12:00' | System | 26 Aug 2020 18:01:20 |
| | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '26 Aug 2020 12:00' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 14:14:38 |
| User entered 'Day 9' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:21:57', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '1be7899c-46b0-4e01-bc7a-67de1796a3f3' | System | 27 Aug 2020 22:22:03 |
| User entered 'Does not interfere with activity (2)' | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:21:59', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '1be7899c-46b0-4e01-bc7a-67de1796a3f3' User entered '27 Aug 2020 16:21' | System | 27 Aug 2020 22:22:03 |
| | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 18:01:20 |
| User entered 'Day 10' | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 27 Aug 2020 22:22:03 |
| User entered 'Day 11' | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:06', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb5f15e9-18ca-4fd7-a8f6-a51e81aa03af' User entered 'None (1)' | System | 30 Aug 2020 00:02:11 |
| | System | 30 Aug 2020 00:02:11 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:08', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bb5f15e9-18ca-4fd7-a8f6-a51e81aa03af' User entered '29 Aug 2020 18:02' | System | 30 Aug 2020 00:02:11 |
| | System | 30 Aug 2020 00:02:11 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 14:15:21 |
| User entered 'Day 8' | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:00:57', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '3566f356-b420-4e5f-958d-28668d5278b2' | System | 26 Aug 2020 18:01:24 |
| User entered 'Some interference with activity (2)' | System | 26 Aug 2020 18:01:24 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:00:59', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '3566f356-b420-4e5f-958d-28668d5278b2' User entered '26 Aug 2020 12:00' | System | 26 Aug 2020 18:01:24 |
| | System | 26 Aug 2020 18:01:24 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '26 Aug 2020 12:00' | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 11:59' | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 14:15:21 |
| User entered 'Day 9' | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:22:10', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '71be6939-63e8-4f39-ae8e-b1b5129dad56' | System | 27 Aug 2020 22:22:18 |
| User entered 'Significant; prevents daily activity (3)' | System | 27 Aug 2020 22:22:18 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:22:13', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '71be6939-63e8-4f39-ae8e-b1b5129dad56' User entered '27 Aug 2020 16:22' | System | 27 Aug 2020 22:22:18 |
| | System | 27 Aug 2020 22:22:18 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 14:15:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 18:01:24 |
| User entered 'Day 10' | System | 26 Aug 2020 18:01:24 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 18:01:24 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 18:01:24 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 27 Aug 2020 22:22:18 |
| User entered 'Day 11' | System | 27 Aug 2020 22:22:18 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:50', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'a0b4094b-894a-4207-8eee-122a7ab05291' User entered 'Some interference with activity (2)' | System | 30 Aug 2020 00:02:55 |
| | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:53', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'a0b4094b-894a-4207-8eee-122a7ab05291' User entered '29 Aug 2020 18:02' | System | 30 Aug 2020 00:02:55 |
| | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 22:22:18 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 22:22:18 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 30 Aug 2020 00:02:55 |
| User entered 'Day 12' | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-30T18:35:44', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd505f2dd-39c5-4182-b03a-222645b2f7ec' | System | 31 Aug 2020 00:38:58 |
| User entered 'Some interference with activity (2)' | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-30T18:35:47', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd505f2dd-39c5-4182-b03a-222645b2f7ec' User entered '30 Aug 2020 18:35' | System | 31 Aug 2020 00:38:58 |
| | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '30 Aug 2020 12:00' | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '31 Aug 2020 11:59' | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 30 Aug 2020 00:02:55 |
| User entered 'Day 13' | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-31T12:00:46', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '692baba3-cb21-417b-b4b0-7d9ba3e4191c' User entered 'No interference with activity (1)' | System | 31 Aug 2020 18:07:10 |
| | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-31T12:00:48', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '692baba3-cb21-417b-b4b0-7d9ba3e4191c' User entered '31 Aug 2020 12:00' | System | 31 Aug 2020 18:07:10 |
| | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '31 Aug 2020 12:00' | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '01 Sep 2020 11:59' | System | 30 Aug 2020 00:02:55 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 31 Aug 2020 00:38:58 |
| User entered 'Day 14' | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-01T12:00:39', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '18cfe6a8-1935-4996-9962-b0bc92dba2e0' | System | 01 Sep 2020 18:00:46 |
| User entered 'No interference with activity (1)' | System | 01 Sep 2020 18:00:46 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-01T12:00:40', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '18cfe6a8-1935-4996-9962-b0bc92dba2e0' User entered '01 Sep 2020 12:00' | System | 01 Sep 2020 18:00:46 |
| | System | 01 Sep 2020 18:00:46 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 31 Aug 2020 18:07:10 |
| User entered 'Day 15' | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-02T12:11:16', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e92be18e-83e4-4a58-8d1a-c1f888e2534d' User entered 'None (0)' | System | 02 Sep 2020 18:11:21 |
| | System | 02 Sep 2020 18:11:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-02T12:11:18', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e92be18e-83e4-4a58-8d1a-c1f888e2534d' User entered '02 Sep 2020 12:11' | System | 02 Sep 2020 18:11:21 |
| | System | 02 Sep 2020 18:11:21 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 24 Aug 2020 18:21:31 |
| User entered 'Day 8' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:00:32', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6eb0d14e-97fb-4ac3-80cc-85b0ab42d17c' User entered 'No (N)' | System | 26 Aug 2020 18:01:14 |
| | System | 26 Aug 2020 18:01:14 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:00:35', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6eb0d14e-97fb-4ac3-80cc-85b0ab42d17c' User entered '26 Aug 2020 12:00' | System | 26 Aug 2020 18:01:14 |
| | System | 26 Aug 2020 18:01:14 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '26 Aug 2020 12:00' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 11:59' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 14:14:38 |
| User entered 'Day 9' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:22:20', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0eef57e4-0e97-416a-826c-369a6691215b' User entered 'No (N)' | System | 27 Aug 2020 22:22:25 |
| | System | 27 Aug 2020 22:22:25 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:22:22', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0eef57e4-0e97-416a-826c-369a6691215b' User entered '27 Aug 2020 16:22' | System | 27 Aug 2020 22:22:25 |
| | System | 27 Aug 2020 22:22:25 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 18:01:20 |
| User entered 'Day 10' | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 18:01:20 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 27 Aug 2020 22:22:03 |
| User entered 'Day 11' | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:14', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '94f6a411-6b21-48fa-b2ca-f261c898a77c' User entered 'No (N)' | System | 30 Aug 2020 00:02:33 |
| | System | 30 Aug 2020 00:02:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:31', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '94f6a411-6b21-48fa-b2ca-f261c898a77c' User entered '29 Aug 2020 18:02' | System | 30 Aug 2020 00:02:33 |
| | System | 30 Aug 2020 00:02:33 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 22:22:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 30 Aug 2020 00:02:43 |
| User entered 'Day 12' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-30T18:35:56', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0d027b3d-b78c-49b2-842c-5d4dc938192d' User entered 'No (N)' | System | 31 Aug 2020 00:39:03 |
| | System | 31 Aug 2020 00:39:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-30T18:35:59', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0d027b3d-b78c-49b2-842c-5d4dc938192d' User entered '30 Aug 2020 18:35' | System | 31 Aug 2020 00:39:03 |
| | System | 31 Aug 2020 00:39:03 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '30 Aug 2020 12:00' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '31 Aug 2020 11:59' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 30 Aug 2020 00:02:43 |
| User entered 'Day 13' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-31T12:00:52', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '320b6f2d-d1ae-49d4-8fc7-5cbf5caed4dc' User entered 'No (N)' | System | 31 Aug 2020 18:07:19 |
| | System | 31 Aug 2020 18:07:19 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-31T12:00:54', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '320b6f2d-d1ae-49d4-8fc7-5cbf5caed4dc' User entered '31 Aug 2020 12:00' | System | 31 Aug 2020 18:07:19 |
| | System | 31 Aug 2020 18:07:19 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '31 Aug 2020 12:00' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '01 Sep 2020 11:59' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 31 Aug 2020 00:38:58 |
| User entered 'Day 14' | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-01T12:00:44', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bd426695-ee64-49a1-9c1b-56f748b674c5' User entered 'No (N)' | System | 01 Sep 2020 18:00:47 |
| | System | 01 Sep 2020 18:00:47 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-01T12:00:45', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'bd426695-ee64-49a1-9c1b-56f748b674c5' | System | 01 Sep 2020 18:00:47 |
| User entered '01 Sep 2020 12:00' | System | 01 Sep 2020 18:00:47 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '01 Sep 2020 12:00' | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '02 Sep 2020 11:59' | System | 31 Aug 2020 00:38:58 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 31 Aug 2020 18:07:10 |
| User entered 'Day 15' | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-02T12:11:22', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd7e5aab0-3993-4c69-a4e2-0e73b827661a' User entered 'No (N)' | System | 02 Sep 2020 18:11:27 |
| | System | 02 Sep 2020 18:11:27 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:03:32

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-09-02T12:11:23', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd7e5aab0-3993-4c69-a4e2-0e73b827661a' User entered '02 Sep 2020 12:11' | System | 02 Sep 2020 18:11:27 |
| | System | 02 Sep 2020 18:11:27 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '02 Sep 2020 12:00' | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '03 Sep 2020 11:59' | System | 31 Aug 2020 18:07:10 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 24 Aug 2020 18:21:31 |
| User entered 'Day 8' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:01:07', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd4517d6b-1d64-4fee-b44c-c17b2593d167' | System | 26 Aug 2020 18:01:38 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)' | System | 26 Aug 2020 18:01:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-26T12:01:10', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd4517d6b-1d64-4fee-b44c-c17b2593d167' User entered '26 Aug 2020 12:01' | System | 26 Aug 2020 18:01:38 |
| | System | 26 Aug 2020 18:01:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '26 Aug 2020 12:00' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(8)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 11:59' | System | 24 Aug 2020 18:21:31 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 14:14:38 |
| User entered 'Day 9' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:22:35', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e97dab45-461b-43dd-b7cd-001e6b3f5e52' | System | 27 Aug 2020 22:22:41 |
| User entered 'Does not interfere with activity (2)' | System | 27 Aug 2020 22:22:41 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-27T16:22:38', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e97dab45-461b-43dd-b7cd-001e6b3f5e52' | System | 27 Aug 2020 22:22:41 |
| User entered '27 Aug 2020 16:22' | System | 27 Aug 2020 22:22:41 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '27 Aug 2020 12:00' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(9)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 11:59' | System | 26 Aug 2020 14:14:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 26 Aug 2020 18:01:38 |
| User entered 'Day 10' | System | 26 Aug 2020 18:01:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '28 Aug 2020 12:00' | System | 26 Aug 2020 18:01:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(10)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 11:59' | System | 26 Aug 2020 18:01:38 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 27 Aug 2020 22:22:41 |
| User entered 'Day 11' | System | 27 Aug 2020 22:22:41 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'cd32feef-f5b8-4ece-9081-e2d66303ed6c' User entered 'Does not interfere with activity (2)' | System | 30 Aug 2020 00:02:43 |
| | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-29T18:02:40', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'cd32feef-f5b8-4ece-9081-e2d66303ed6c' User entered '29 Aug 2020 18:02' | System | 30 Aug 2020 00:02:43 |
| | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '29 Aug 2020 12:00' | System | 27 Aug 2020 22:22:41 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(11)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '30 Aug 2020 11:59' | System | 27 Aug 2020 22:22:41 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 30 Aug 2020 00:02:43 |
| User entered 'Day 12' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:03:32

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-30T18:35:51', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '5a24cd6b-046a-46b0-b605-9dc12b2e4c2c' User entered 'None (1)' | System | 31 Aug 2020 00:39:01 |
| | System | 31 Aug 2020 00:39:01 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-08-30T18:35:53', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '5a24cd6b-046a-46b0-b605-9dc12b2e4c2c' User entered '30 Aug 2020 18:35' | System | 31 Aug 2020 00:39:01 |
| | System | 31 Aug 2020 00:39:01 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Open Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '30 Aug 2020 12:00' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Diary Dose 1 (1)

Form: Underarm Gland_Day(12)

Generated On: 11 Aug 2021 22:03:32

[PC Close Date and Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| User entered '31 Aug 2020 11:59' | System | 30 Aug 2020 00:02:43 |

US3142243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 28 Aug 2020 00:02:52 |

US3142243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '27 Aug 2020' | Jill York (b) (4) | 28 Aug 2020 00:02:52 |

US3142243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Contact Made (CONTACT MADE)' | Jill York (b) (4) | 28 Aug 2020 00:02:52 |

US3142243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 28 Aug 2020 00:02:52 |

US3142243

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 28 Aug 2020 00:03:00 |

US3142243

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '1' | System | 28 Aug 2020 00:03:00 |

US3142243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 23 Oct 2020 19:49:47 |

US3142243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '3 Sep 2020' | Jill York (b) (4) | 23 Oct 2020 19:49:47 |

US3142243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Contact Made (CONTACT MADE)' | Jill York (b) (4) | 23 Oct 2020 19:49:47 |

US3142243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 23 Oct 2020 19:49:47 |

US3142243

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:12:27 |

US3142243

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'I' | System | 17 Sep 2020 17:12:27 |

US3142243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 23 Oct 2020 19:50:38 |

US3142243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '10 Sep 2020' | Jill York (b) (4) | 23 Oct 2020 19:50:38 |

US3142243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Contact Made (CONTACT MADE)' | Jill York (b) (4) | 23 Oct 2020 19:50:38 |

US3142243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 23 Oct 2020 19:50:38 |

US3142243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:12:36 |

US3142243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '1' | System | 17 Sep 2020 17:12:36 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Nov 2020 07:05:11 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Information is correct. Sample now recorded in EDC' (Site from DM). | Meghan York (b) (4) (b) (4) | 21 Oct 2020 19:19:26 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 08:38:42 |
| User entered 'Yes (Y)' | Meghan York (b) (4) (b) (4) | 17 Sep 2020 17:12:53 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' answered with 'Data for this visit is now entered into EDC' (Site from DM). | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 06:38:10 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09NOV2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM). | Meghan York (b) (4) (b) (4) | 02 Dec 2020 22:24:12 |
| User entered '16 Sep 2020' | (b) (4), (b) (6) | 18 Nov 2020 10:24:09 |
| | Meghan York (b) (4) (b) (4) | 17 Sep 2020 17:12:53 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Clinic (Clinic)' | Meghan York (b) (4) | 17 Sep 2020 17:12:53 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'VISIT2' | System | 17 Sep 2020 17:12:53 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Meghan York (b) (4) (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16 Sep 2020' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:49' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '16 Sep 2020 16:49' | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '98.0' F | Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Other (Other)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'temporal' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '82' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'bpm' | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '14' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'breaths/min' | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '133' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'mmHg' | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '93' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'mmHg' | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Meghan York (b) (4) (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System). | (b) (4) | 19 Oct 2020 20:33:28 |
| User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System). | System | 19 Oct 2020 20:33:11 |
| User entered 'No (N)' | Meghan York (b) (4) | 17 Sep 2020 17:13:54 |
| | (b) (4) | |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 15:11:52 |
| Query 'Per DM:Please updated the data.' answered with 'post dose vitals were not taken ' (Site from DM). | Meghan York (b) (4) | 19 Oct 2020 20:34:24 |
| User entered empty; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:11 |
| User opened query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 14:17:25 |
| User entered empty. | Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 15:11:41 |
| Query 'Per DM:Please updated the data.' answered with 'post dose vitals were not taken ' (Site from DM). | Meghan York (b) (4) | 19 Oct 2020 20:34:15 |
| User entered empty; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:11 |
| User opened query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 14:17:40 |
| User entered empty. | Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 19 Oct 2020 20:33:28 |
| User entered 'bpm' | System | 19 Oct 2020 20:33:11 |
| User entered empty. | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM:Please updated the data.' (Site from DM). | (b) (4) | |
| Query 'Per DM:Please updated the data.' answered with 'post dose vitals were not taken ' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 15:11:43 |
| Query 'Per DM:Please updated the data.' answered with 'post dose vitals were not taken ' (Site from DM). | Meghan York (b) (4) | 19 Oct 2020 20:34:10 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:28 |
| User opened query 'Per DM:Please updated the data.' (Site from DM). | (b) (4) | |
| User entered empty. | (b) (4), (b) (6) | 25 Sep 2020 14:17:49 |
| | Meghan York (b) (4) | 17 Sep 2020 17:13:54 |
| | (b) (4) | |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 19 Oct 2020 20:33:28 |
| User entered 'breaths/min' | System | 19 Oct 2020 20:33:11 |
| User entered empty. | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 15:11:46 |
| Query 'Per DM:Please updated the data.' answered with 'post dose vitals were not taken ' (Site from DM). | Meghan York (b) (4) | 19 Oct 2020 20:34:09 |
| User entered empty; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:11 |
| User opened query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 14:17:59 |
| User entered empty. | Meghan York (b) (4) | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 19 Oct 2020 20:33:28 |
| User entered 'mmHg' | System | 19 Oct 2020 20:33:11 |
| User entered empty. | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM:Please updated the data.' (Site from DM). | (b) (4) | |
| Query 'Per DM:Please updated the data.' answered with 'post dose vitals were not taken ' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 15:11:47 |
| Query 'Per DM:Please updated the data.' answered with 'post dose vitals were not taken ' (Site from DM). | Meghan York (b) (4) | 19 Oct 2020 20:34:06 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:33:28 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | |
| User opened query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 19 Oct 2020 20:33:11 |
| User opened query 'Per DM:Please updated the data.' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 14:18:09 |
| User entered empty. | Meghan York (b) (4) | 17 Sep 2020 17:13:54 |
| | (b) (4) | |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 19 Oct 2020 20:33:28 |
| User entered 'mmHg' | System | 19 Oct 2020 20:33:11 |
| User entered empty. | System | 17 Sep 2020 17:13:54 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:14:07 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16 Sep 2020' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:14:07 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

If No, reason not given

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Other (OTHER)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

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) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per CDM: :Was study treatment given?' No" and "Reason is recorded as HAD A REACTION TO THE FIRST DOSE". Please update an AE form accordingly. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 05:22:04 |
| Query 'Per CDM: :Was study treatment given?' No" and "Reason is recorded as HAD A REACTION TO THE FIRST DOSE". Please update an AE form accordingly. Thank you.' answered with 'UPDATED' (Site from DM). | Jill York (b) (4) | 12 Apr 2021 20:22:33 |
| User entered 'subject has multiple reactions to first dose. Subject declined second blinded vaccine/placebo and PI agreed. Site to add AEs to EDC per source.' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 19:31:07 |
| User opened query 'Per CDM: :Was study treatment given?' No" and "Reason is recorded as HAD A REACTION TO THE FIRST DOSE". Please update an AE form accordingly. Thank you.' (Site from DM). | (b) (4), (b) (6) | 24 Sep 2020 04:15:32 |
| User entered 'Had a reaction to the first dose' | Meghan York (b) (4) (b) (4) | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:32

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 17 Sep 2020 17:14:56 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 21 Oct 2020 19:19:45 |
| User entered 'No (N)' | (b) (4) | |
| | Meghan York (b) (4) | 21 Oct 2020 19:07:16 |
| | (b) (4) | |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 21 Oct 2020 19:19:45 |
| User entered empty. | (b) (4) | |
| | Meghan York (b) (4) | 21 Oct 2020 19:07:16 |
| | (b) (4) | |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '17:00' reason for change: Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 21 Oct 2020 19:19:45 |
| User entered empty. | (b) (4) | |
| | Meghan York (b) (4) | 21 Oct 2020 19:07:16 |
| | (b) (4) | |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '16 Sep 2020 17:00' | System | 21 Oct 2020 19:19:45 |
| User entered empty. | System | 21 Oct 2020 19:07:16 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:03:32

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Nov 2020 16:31:53 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' answered with 'time not provided in source ' (Site from DM). | Meghan York (b) (4) (b) (4) | 29 Oct 2020 20:03:00 |
| User entered '16 Sep 2020' reason for change: Data Entry Error | Meghan York (b) (4) (b) (4) | 29 Oct 2020 20:02:38 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Sep-2020 is reported under Visit 2 Day 29 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 09:58:16 |
| User entered empty. | Meghan York (b) (4) (b) (4) | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Meghan York (b) (4) (b) (4) | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Meghan York (b) (4) | 29 Oct 2020 20:02:38 |
| User entered 'No (N)' | (b) (4) | |
| | Meghan York (b) (4) | 21 Oct 2020 19:07:23 |
| | (b) (4) | |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 03 Nov 2020 16:32:22 |
| Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered with 'collection time was not provided in source ' (Site from System). | Meghan York (b) (4) | 29 Oct 2020 20:03:28 |
| User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System). | System | 29 Oct 2020 20:02:38 |
| User entered empty. | Meghan York (b) (4) | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:03:32

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Meghan York (b) (4) (b) (4) | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Meghan York (b) (4) (b) (4) | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:32

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered empty. | System | 21 Oct 2020 19:07:23 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 17 Sep 2020 17:15:13 |

US3142243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '1' | System | 17 Sep 2020 17:15:13 |

US3142243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 22 Oct 2020 19:38:33 |

US3142243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:38:33 |

US3142243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:38:33 |

US3142243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:38:33 |

US3142243

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 22 Oct 2020 19:38:40 |

US3142243

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'I' | System | 22 Oct 2020 19:38:40 |

US3142243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 22 Oct 2020 19:38:58 |

US3142243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:38:58 |

US3142243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:38:58 |

US3142243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:38:58 |

US3142243

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 22 Oct 2020 19:39:04 |

US3142243

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'I' | System | 22 Oct 2020 19:39:04 |

US3142243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 22 Oct 2020 19:39:15 |

US3142243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:39:15 |

US3142243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:39:15 |

US3142243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 22 Oct 2020 19:39:15 |

US3142243

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 22 Oct 2020 19:39:21 |

US3142243

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'I' | System | 22 Oct 2020 19:39:21 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:22 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '9 Nov 2020' | Meghan York (b) (4) | 02 Dec 2020 22:22:22 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Clinic (Clinic)' | (b) (4) Meghan York (b) (4) (b) (4) | 02 Dec 2020 22:22:22 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User entered 'VISIT3' | System | 02 Dec 2020 22:22:22 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '9 Nov 2020' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:41' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User entered '9 Nov 2020 16:41' | System | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '98.4' F | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Other (Other)' | Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'temporal' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '71' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User entered 'bpm' | System | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '10' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User entered 'breaths/min' | System | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '162' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User entered 'mmHg' | System | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Dec 2020 19:09:51 |
| Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System). | Meghan York (b) (4) (b) (4) | 02 Dec 2020 22:23:08 |
| User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 02 Dec 2020 22:22:58 |
| User entered '103' | Meghan York (b) (4) (b) (4) | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |
| User entered 'mmHg' | System | 02 Dec 2020 22:22:58 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:32

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:34 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:23:17 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:32

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '9 Nov 2020' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:23:17 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:23:36 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '9 Nov 2020' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:23:36 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '16:52' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:23:36 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:32

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '9 Nov 2020 16:52' | System | 02 Dec 2020 22:23:36 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | (b) (4) Meghan York (b) (4) | 02 Dec 2020 22:23:41 |

US3142243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered '1' | System | 02 Dec 2020 22:23:41 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 64' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-10-22T07:05:09', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'b24c263e-767b-41d4-8701-22eff76e6fd3' | System | 22 Oct 2020 13:05:29 |
| User entered 'No (N)' | System | 22 Oct 2020 13:05:29 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-10-22T07:05:18', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'b24c263e-767b-41d4-8701-22eff76e6fd3' | System | 22 Oct 2020 13:05:29 |
| User entered 'No (N)' | System | 22 Oct 2020 13:05:29 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-10-22T07:05:27', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'b24c263e-767b-41d4-8701-22eff76e6fd3' User entered '22 Oct 2020 07:05:27' | System | 22 Oct 2020 13:05:29 |
| | System | 22 Oct 2020 13:05:29 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '19 Oct 2020 00:01' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '23 Oct 2020 23:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 71' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-10-30T18:03:27', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '7ba8988a-5c5f-4ed2-bff2-a14b8f7b4e92' | System | 31 Oct 2020 00:03:55 |
| User entered 'No (N)' | System | 31 Oct 2020 00:03:55 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-10-30T18:03:47', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '7ba8988a-5c5f-4ed2-bff2-a14b8f7b4e92' | System | 31 Oct 2020 00:03:55 |
| User entered 'No (N)' | System | 31 Oct 2020 00:03:55 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-10-30T18:03:51', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '7ba8988a-5c5f-4ed2-bff2-a14b8f7b4e92' User entered '30 Oct 2020 18:03:51' | System | 31 Oct 2020 00:03:55 |
| | System | 31 Oct 2020 00:03:55 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '26 Oct 2020 00:01' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '30 Oct 2020 23:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 78' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-06T18:04:20', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6071a0dc-835c-4a6c-8763-e59eab3e54f7' User entered 'No (N)' | System | 07 Nov 2020 01:04:48 |
| | System | 07 Nov 2020 01:04:48 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-06T18:04:43', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6071a0dc-835c-4a6c-8763-e59eab3e54f7' User entered 'No (N)' | System | 07 Nov 2020 01:04:48 |
| | System | 07 Nov 2020 01:04:48 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-06T18:04:46', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '6071a0dc-835c-4a6c-8763-e59eab3e54f7' User entered '06 Nov 2020 18:04:46' | System | 07 Nov 2020 01:04:48 |
| | System | 07 Nov 2020 01:04:48 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '02 Nov 2020 00:01' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 02:01:49 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '06 Nov 2020 23:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered 'Day 92' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '16 Nov 2020 00:01' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 23:25:02 |
| Data entry locked. | System | 19 Aug 2020 23:30:32 |
| User entered '20 Nov 2020 23:59' | System | 19 Aug 2020 23:30:32 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-23T18:34:51', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '8f6a3807-bf36-4852-80d4-695d6ca11284' User entered 'No (N)' | System | 24 Nov 2020 01:35:05 |
| | System | 24 Nov 2020 01:35:05 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-23T18:34:57', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '8f6a3807-bf36-4852-80d4-695d6ca11284' User entered 'No (N)' | System | 24 Nov 2020 01:35:05 |
| | System | 24 Nov 2020 01:35:05 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-23T18:35:01', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '8f6a3807-bf36-4852-80d4-695d6ca11284' User entered '23 Nov 2020 18:35:01' | System | 24 Nov 2020 01:35:05 |
| | System | 24 Nov 2020 01:35:05 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-28T13:32:03', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ad173080-d017-49f7-96b4-b6ed9880056c' User entered 'No (N)' | System | 28 Nov 2020 20:32:16 |
| | System | 28 Nov 2020 20:32:16 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-28T13:32:08', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ad173080-d017-49f7-96b4-b6ed9880056c' User entered 'No (N)' | System | 28 Nov 2020 20:32:16 |
| | System | 28 Nov 2020 20:32:16 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-11-28T13:32:12', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ad173080-d017-49f7-96b4-b6ed9880056c' User entered '28 Nov 2020 13:32:12' | System | 28 Nov 2020 20:32:16 |
| | System | 28 Nov 2020 20:32:16 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-06T12:00:46', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '8b9af7a1-3df0-4e9a-9079-779adb916ba8' User entered 'No (N)' | System | 06 Dec 2020 19:01:07 |
| | System | 06 Dec 2020 19:01:07 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-06T12:01:01', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '8b9af7a1-3df0-4e9a-9079-779adb916ba8' User entered 'No (N)' | System | 06 Dec 2020 19:01:07 |
| | System | 06 Dec 2020 19:01:07 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-06T12:01:05', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '8b9af7a1-3df0-4e9a-9079-779adb916ba8' User entered '06 Dec 2020 12:01:05' | System | 06 Dec 2020 19:01:07 |
| | System | 06 Dec 2020 19:01:07 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-12T10:11:49', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd6989f77-4846-4916-96c8-2760de592c53' | System | 12 Dec 2020 17:11:59 |
| User entered 'No (N)' | System | 12 Dec 2020 17:11:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-12T10:11:52', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd6989f77-4846-4916-96c8-2760de592c53' | System | 12 Dec 2020 17:11:59 |
| User entered 'No (N)' | System | 12 Dec 2020 17:11:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-12T10:11:55', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd6989f77-4846-4916-96c8-2760de592c53' | System | 12 Dec 2020 17:11:59 |
| User entered '12 Dec 2020 10:11:55' | System | 12 Dec 2020 17:11:59 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-20T12:00:43', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd29e703a-10a0-46c5-b7d7-6f9be8dc2ef1' User entered 'No (N)' | System | 20 Dec 2020 19:00:55 |
| | System | 20 Dec 2020 19:00:55 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-20T12:00:51', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd29e703a-10a0-46c5-b7d7-6f9be8dc2ef1' User entered 'No (N)' | System | 20 Dec 2020 19:00:55 |
| | System | 20 Dec 2020 19:00:55 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-20T12:00:53', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'd29e703a-10a0-46c5-b7d7-6f9be8dc2ef1' User entered '20 Dec 2020 12:00:53' | System | 20 Dec 2020 19:00:55 |
| | System | 20 Dec 2020 19:00:55 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-25T05:34:03', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '15089012-ba0a-4cde-ade4-3df0792ac0b0' User entered 'No (N)' | System | 25 Dec 2020 12:34:12 |
| | System | 25 Dec 2020 12:34:12 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-25T05:34:05', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '15089012-ba0a-4cde-ade4-3df0792ac0b0' User entered 'No (N)' | System | 25 Dec 2020 12:34:12 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2020-12-25T05:34:07', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '15089012-ba0a-4cde-ade4-3df0792ac0b0' User entered '25 Dec 2020 05:34:07' | System | 25 Dec 2020 12:34:12 |
| | System | 25 Dec 2020 12:34:12 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-01T19:30:45', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'fec0f6b0-e327-4236-9a4a-8e6ec3d4ad7d' | System | 02 Jan 2021 02:31:08 |
| User entered 'No (N)' | System | 02 Jan 2021 02:31:08 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-01T19:30:50', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'fec0f6b0-e327-4236-9a4a-8e6ec3d4ad7d' | System | 02 Jan 2021 02:31:08 |
| User entered 'No (N)' | System | 02 Jan 2021 02:31:08 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-01T19:30:53', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'fec0f6b0-e327-4236-9a4a-8e6ec3d4ad7d' User entered '01 Jan 2021 19:30:53' | System | 02 Jan 2021 02:31:08 |
| | System | 02 Jan 2021 02:31:08 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-11T20:49:05', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '744bd873-54e4-4f54-b952-eb307bf8059b' User entered 'No (N)' | System | 12 Jan 2021 03:49:15 |
| | System | 12 Jan 2021 03:49:15 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-11T20:49:09', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '744bd873-54e4-4f54-b952-eb307bf8059b' User entered 'No (N)' | System | 12 Jan 2021 03:49:15 |
| | System | 12 Jan 2021 03:49:15 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-11T20:49:12', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '744bd873-54e4-4f54-b952-eb307bf8059b' User entered '11 Jan 2021 20:49:12' | System | 12 Jan 2021 03:49:15 |
| | System | 12 Jan 2021 03:49:15 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-16T12:53:50', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e24423ea-0574-4d6d-aa9d-0b3713f3f258' User entered 'No (N)' | System | 16 Jan 2021 19:54:02 |
| | System | 16 Jan 2021 19:54:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-16T12:53:56', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e24423ea-0574-4d6d-aa9d-0b3713f3f258' User entered 'No (N)' | System | 16 Jan 2021 19:54:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-16T12:54:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'e24423ea-0574-4d6d-aa9d-0b3713f3f258' User entered '16 Jan 2021 12:54:00' | System | 16 Jan 2021 19:54:02 |
| | System | 16 Jan 2021 19:54:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-22T05:49:20', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '62512738-9f8f-454f-9024-f0a974a2df95' | System | 22 Jan 2021 12:49:29 |
| User entered 'No (N)' | System | 22 Jan 2021 12:49:29 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-22T05:49:24', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '62512738-9f8f-454f-9024-f0a974a2df95' | System | 22 Jan 2021 12:49:29 |
| User entered 'No (N)' | System | 22 Jan 2021 12:49:29 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-22T05:49:27', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '62512738-9f8f-454f-9024-f0a974a2df95' User entered '22 Jan 2021 05:49:27' | System | 22 Jan 2021 12:49:29 |
| | System | 22 Jan 2021 12:49:29 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-29T15:32:36', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9c2b6e1b-1690-47e0-a608-3836ac1db349' | System | 29 Jan 2021 22:32:43 |
| User entered 'No (N)' | System | 29 Jan 2021 22:32:43 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-29T15:32:38', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9c2b6e1b-1690-47e0-a608-3836ac1db349' | System | 29 Jan 2021 22:32:43 |
| User entered 'No (N)' | System | 29 Jan 2021 22:32:43 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-01-29T15:32:41', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '9c2b6e1b-1690-47e0-a608-3836ac1db349' User entered '29 Jan 2021 15:32:41' | System | 29 Jan 2021 22:32:43 |
| | System | 29 Jan 2021 22:32:43 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-07T13:38:07', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'a242ff66-56aa-4463-b690-d9b8fe17707a' User entered 'No (N)' | System | 07 Feb 2021 20:38:13 |
| | System | 07 Feb 2021 20:38:13 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-07T13:38:09', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'a242ff66-56aa-4463-b690-d9b8fe17707a' User entered 'No (N)' | System | 07 Feb 2021 20:38:13 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-07T13:38:11', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'a242ff66-56aa-4463-b690-d9b8fe17707a' User entered '07 Feb 2021 13:38:11' | System | 07 Feb 2021 20:38:13 |
| | System | 07 Feb 2021 20:38:13 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-12T17:20:28', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'b51c8702-ba19-4079-b44e-7dec15452bef' User entered 'No (N)' | System | 13 Feb 2021 00:21:48 |
| | System | 13 Feb 2021 00:21:48 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-12T17:20:30', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'b51c8702-ba19-4079-b44e-7dec15452bef' User entered 'No (N)' | System | 13 Feb 2021 00:21:48 |
| | System | 13 Feb 2021 00:21:48 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-12T17:20:32', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'b51c8702-ba19-4079-b44e-7dec15452bef' User entered '12 Feb 2021 17:20:32' | System | 13 Feb 2021 00:21:48 |
| | System | 13 Feb 2021 00:21:48 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-19T07:49:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '043b0a86-3d44-42e9-8de7-f24efbc35200' | System | 19 Feb 2021 14:49:08 |
| User entered 'No (N)' | System | 19 Feb 2021 14:49:08 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-19T07:49:02', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '043b0a86-3d44-42e9-8de7-f24efbc35200' User entered 'No (N)' | System | 19 Feb 2021 14:49:08 |
| | System | 19 Feb 2021 14:49:08 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-19T07:49:05', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '043b0a86-3d44-42e9-8de7-f24efbc35200' User entered '19 Feb 2021 07:49:05' | System | 19 Feb 2021 14:49:08 |
| | System | 19 Feb 2021 14:49:08 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-27T11:49:14-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0101f4d9-a0b7-49a6-8138-14f8dd402efb' | System | 27 Feb 2021 18:49:23 |
| User entered 'No (N)' | System | 27 Feb 2021 18:49:23 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-27T11:49:16-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0101f4d9-a0b7-49a6-8138-14f8dd402efb' | System | 27 Feb 2021 18:49:23 |
| User entered 'No (N)' | System | 27 Feb 2021 18:49:23 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-27T11:49:19-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '0101f4d9-a0b7-49a6-8138-14f8dd402efb' User entered '27 Feb 2021 18:49:19' | System | 27 Feb 2021 18:49:23 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-08T20:49:19-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '337df314-be0a-4088-9930-2f73d7458c53' | System | 09 Mar 2021 03:51:50 |
| User entered 'No (N)' | System | 09 Mar 2021 03:51:50 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-08T20:49:23-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '337df314-be0a-4088-9930-2f73d7458c53' | System | 09 Mar 2021 03:51:50 |
| User entered 'No (N)' | System | 09 Mar 2021 03:51:50 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-08T20:49:25-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '337df314-be0a-4088-9930-2f73d7458c53' User entered '08 Mar 2021 20:49:25' | System | 09 Mar 2021 03:51:50 |
| | System | 09 Mar 2021 03:51:50 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-12T17:35:39-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '31becd2e-b389-4f03-9067-b29faf0a88ba' User entered 'No (N)' | System | 13 Mar 2021 00:35:49 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-12T17:35:41-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '31becd2e-b389-4f03-9067-b29faf0a88ba' User entered 'No (N)' | System | 13 Mar 2021 00:35:49 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-12T17:35:43-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '31becd2e-b389-4f03-9067-b29faf0a88ba' User entered '12 Mar 2021 17:35:43' | System | 13 Mar 2021 00:35:49 |
| | System | 13 Mar 2021 00:35:49 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-21T19:33:54-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '44e72535-a8a2-46d5-8da6-18430186544a' User entered 'No (N)' | System | 22 Mar 2021 01:34:12 |
| | System | 22 Mar 2021 01:34:12 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-21T19:33:56-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '44e72535-a8a2-46d5-8da6-18430186544a' User entered 'No (N)' | System | 22 Mar 2021 01:34:12 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-21T19:34:00-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '44e72535-a8a2-46d5-8da6-18430186544a' User entered '21 Mar 2021 19:34:00' | System | 22 Mar 2021 01:34:12 |
| | System | 22 Mar 2021 01:34:12 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-26T16:27:55-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '4467380d-6641-4f70-a3b9-2befc07057fe' User entered 'No (N)' | System | 26 Mar 2021 22:28:29 |
| | System | 26 Mar 2021 22:28:29 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-26T16:27:57-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '4467380d-6641-4f70-a3b9-2befc07057fe' User entered 'No (N)' | System | 26 Mar 2021 22:28:29 |
| | System | 26 Mar 2021 22:28:29 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-03-26T16:28:27-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '4467380d-6641-4f70-a3b9-2befc07057fe' User entered '26 Mar 2021 16:28:27' | System | 26 Mar 2021 22:28:29 |
| | System | 26 Mar 2021 22:28:29 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-04T09:29:37-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '73917dca-0411-459c-994b-c91449edaf14' | System | 04 Apr 2021 15:29:44 |
| User entered 'No (N)' | System | 04 Apr 2021 15:29:44 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-04T09:29:38-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '73917dca-0411-459c-994b-c91449edaf14' | System | 04 Apr 2021 15:29:44 |
| User entered 'No (N)' | System | 04 Apr 2021 15:29:44 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-04T09:29:41-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '73917dca-0411-459c-994b-c91449edaf14' | System | 04 Apr 2021 15:29:44 |
| User entered '04 Apr 2021 09:29:41' | System | 04 Apr 2021 15:29:44 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-10T12:15:09-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '70d9680d-88b5-4481-aa71-252c79e5ad0b' User entered 'No (N)' | System | 10 Apr 2021 18:15:17 |
| | System | 10 Apr 2021 18:15:17 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-10T12:15:11-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '70d9680d-88b5-4481-aa71-252c79e5ad0b' | System | 10 Apr 2021 18:15:17 |
| User entered 'No (N)' | System | 10 Apr 2021 18:15:17 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-10T12:15:13-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '70d9680d-88b5-4481-aa71-252c79e5ad0b' | System | 10 Apr 2021 18:15:17 |
| User entered '10 Apr 2021 12:15:13' | System | 10 Apr 2021 18:15:17 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-19T20:13:18-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '520b9622-d450-4bb3-a53f-a54d8cfbab9b' User entered 'No (N)' | System | 20 Apr 2021 02:13:31 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-19T20:13:21-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '520b9622-d450-4bb3-a53f-a54d8cfbab9b' User entered 'No (N)' | System | 20 Apr 2021 02:13:31 |
| | System | 20 Apr 2021 02:13:31 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-19T20:13:23-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '520b9622-d450-4bb3-a53f-a54d8cfbab9b' User entered '19 Apr 2021 20:13:23' | System | 20 Apr 2021 02:13:31 |
| | System | 20 Apr 2021 02:13:31 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-24T12:21:43-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '25050125-28bc-45a1-a4f7-e23a5387c6e4' | System | 24 Apr 2021 18:21:48 |
| User entered 'No (N)' | System | 24 Apr 2021 18:21:48 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

Have you been exposed to someone with 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 (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-24T12:21:45-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '25050125-28bc-45a1-a4f7-e23a5387c6e4' | System | 24 Apr 2021 18:21:48 |
| User entered 'No (N)' | System | 24 Apr 2021 18:21:48 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-04-24T12:21:47-06:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: '25050125-28bc-45a1-a4f7-e23a5387c6e4' User entered '24 Apr 2021 12:21:47' | System | 24 Apr 2021 18:21:48 |
| | System | 24 Apr 2021 18:21:48 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:32

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:25:02 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 19 Nov 2020 23:25:02 |

US3142243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:03:32

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-27T11:49:27-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ff407981-f570-4be9-8205-8f3365754716' | System | 27 Feb 2021 18:49:36 |
| User entered 'No (N)' | System | 27 Feb 2021 18:49:36 |

US3142243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:03:32

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:03:40 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D7C041E5-81D6-41FA-99EC-0718CF1004E2)', Time: '2021-02-27T11:49:30-07:00', User OID: 'PatientReportedOutcome (US3142243)', ODM File OID: 'ff407981-f570-4be9-8205-8f3365754716' | System | 27 Feb 2021 18:49:36 |
| User entered '27 Feb 2021 18:49:30' | System | 27 Feb 2021 18:49:36 |

US3142243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 10 Dec 2020 22:24:33 |

US3142243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '10 Nov 2020' | Jami Wagner (b) (4) | 10 Dec 2020 22:24:33 |

US3142243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 10 Dec 2020 22:24:33 |

US3142243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jami Wagner (b) (4) | 10 Dec 2020 22:24:33 |

US3142243

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 10 Dec 2020 22:23:48 |

US3142243

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 06:50:28 |
| User entered 'I' | System | 10 Dec 2020 22:23:48 |

US3142243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 15 Dec 2020 22:49:39 |

US3142243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '15 Dec 2020' | Jami Wagner (b) (4) | 15 Dec 2020 22:49:39 |

US3142243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 15 Dec 2020 22:49:39 |

US3142243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jami Wagner (b) (4) | 15 Dec 2020 22:49:39 |

US3142243

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 15 Dec 2020 22:49:43 |

US3142243

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User entered 'I' | System | 15 Dec 2020 22:49:43 |

US3142243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | (b) (4) | 18 Feb 2021 22:02:23 |
| User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System | 18 Feb 2021 22:01:58 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 18 Feb 2021 22:01:58 |
| | (b) (4) | |

US3142243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '11 Feb 2021' | Jami Wagner (b) (4) | 18 Feb 2021 22:01:58 |

US3142243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) | |
| reason for change: Data Entry Error | Jami Wagner (b) (4) | 18 Feb 2021 22:02:23 |
| User entered empty. | (b) (4) | |
| | Jami Wagner (b) (4) | 18 Feb 2021 22:01:58 |
| | (b) (4) | |

US3142243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jami Wagner (b) (4) | 18 Feb 2021 22:01:58 |

US3142243

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 18 Feb 2021 22:02:31 |

US3142243

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User entered '1' | System | 18 Feb 2021 22:02:31 |

US3142243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 01 Apr 2021 22:53:49 |

US3142243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '15 Feb 2021' | Jami Wagner (b) (4) | 01 Apr 2021 22:53:49 |

US3142243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Contact Made (CONTACT MADE)' | Jami Wagner (b) (4) | 01 Apr 2021 22:53:49 |

US3142243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:03:32

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jami Wagner (b) (4) | 01 Apr 2021 22:53:49 |

US3142243

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jami Wagner (b) (4) | 01 Apr 2021 22:54:17 |

US3142243

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 15:18:03 |
| User entered 'I' | System | 01 Apr 2021 22:54:17 |

US3142243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Lisa Jackson (b) (4) | 05 Apr 2021 19:52:26 |
| | (b) (4) | |

US3142243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 05 Apr 2021 19:52:26 |
| | (b) (4) | |

US3142243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Lisa Jackson (b) (4) | 05 Apr 2021 19:52:26 |
| | (b) (4) | |

US3142243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:32

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 05 Apr 2021 19:52:26 |

US3142243

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Lisa Jackson (b) (4) | 05 Apr 2021 19:53:07 |
| | (b) (4) | |

US3142243

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:32

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 19:53:07 |

US3142243

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:03:32

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:39:48 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE PAIN persist beyond Day 7 (start date: Day 1; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 08:26:39 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 14). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | | 12 Apr 2021 08:26:37 |
| Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE PAIN persist beyond Day 7 (start date: Day 1; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'data now entered ' (Site from DM). | Jill York (b) (4) | 07 Apr 2021 19:46:15 |
| Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 14). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'data now entered ' (Site from DM). | Jill York (b) (4) | 07 Apr 2021 19:45:54 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 6; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 09:30:33 |

US3142243

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:03:32

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 6; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'subject unresponsive - unable to provide details' (Site from DM). | Jill York (b) (4) | 06 Apr 2021 19:24:30 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of UNDERARM GLAND SWELLING OR TENDERNESS persist beyond Day 7 (start date: Day 6; end date: Day 11). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 04:57:43 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of INJECTION SITE PAIN persist beyond Day 7 (start date: Day 1; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | | 10 Feb 2021 04:57:36 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 14). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | | 10 Feb 2021 04:57:29 |
| User entered 'Yes (Y)' | Meghan York (b) (4) (b) (4) | 21 Oct 2020 19:07:49 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Apr 2021 21:21:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Apr 2021 21:21:30 |
| Data point term sent to Coder | System | 12 Apr 2021 20:06:38 |
| Coding entries removed. | Jill York (b) (4) | 12 Apr 2021 20:06:31 |
| User entered 'fatigue' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:06:31 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 06:21:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Apr 2021 06:21:40 |
| Data point term sent to Coder | System | 07 Apr 2021 19:41:48 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'fatigue persisting past day 7' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'No (N)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'No (N)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '26 Aug 2020' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:06:31 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered '19 Aug 2020' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 12 Apr 2021 20:06:31 |
| Query 'Data is required. Please provide.' answered with 'time unknown ' (Site from System). | Jill York (b) (4) | 07 Apr 2021 19:41:57 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'No (N)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '07 Sep 2020' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:06:31 |
| User entered '28 Aug 2020' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 12 Apr 2021 20:06:31 |
| Query 'Data is required. Please provide.' answered with 'time unknown ' (Site from System). | Jill York (b) (4) | 07 Apr 2021 19:42:11 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:06:31 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'No (N)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'None (NONE)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

None

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | (b) (4) System | 07 Apr 2021 19:41:46 |
| User entered '1' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered '0' | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:41:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:41:46 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Jill York (b) (4) | 07 Apr 2021 19:41:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:21:09 |
| User entered empty. | Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | (b) (4) Jill York (b) (4) | 06 Apr 2021 19:21:09 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 07 Apr 2021 19:41:46 |

US3142243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 07 Apr 2021 19:41:46 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| | | |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Apr 2021 21:22:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 12 Apr 2021 21:22:34 |
| Data point term sent to Coder | System | 12 Apr 2021 20:10:47 |
| User entered 'site injection pain' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '20 Aug 2020' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 16 Apr 2021 17:22:08 |
| Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System). | Jill York (b) (4) | 12 Apr 2021 20:10:01 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Apr 2021 20:09:51 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User entered empty. | System | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '29 Aug 2020' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) (b) (4), (b) (6) | 16 Apr 2021 17:22:10 |
| Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System). | Jill York (b) (4) | 12 Apr 2021 20:10:14 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Apr 2021 20:09:51 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User entered empty. | System | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Apr 2021 20:10:46 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:10:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Apr 2021 20:09:51 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Apr 2021 20:10:46 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 12 Apr 2021 20:10:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | Jill York (b) (4) | 12 Apr 2021 20:10:46 |
| User entered empty. | System | 12 Apr 2021 20:09:51 |
| | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 12 Apr 2021 20:10:46 |
| User entered 'None (NONE)' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:10:46 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 12 Apr 2021 20:09:51 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'I' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[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 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User entered '0' | System | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| User entered '0' | System | 12 Apr 2021 20:09:51 |

US3142243

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:30 |
| | | |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Apr 2021 11:14:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 15 Apr 2021 11:14:18 |
| Data point term sent to Coder | System | 12 Apr 2021 20:12:51 |
| User entered 'left armpit swelling' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Jill York (b) (4) | 12 Apr 2021 20:15:07 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '22 Aug 2020' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User entered empty. | System | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '07 Sep 2020' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User entered empty. | System | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Related (RELATED)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Not Related (NOT RELATED)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'I' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[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 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User entered '0' | System | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| User entered '0' | System | 12 Apr 2021 20:12:00 |

US3142243

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:38 |
| | | |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| | | |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Feeling abnormal, LLT: Foggy feeling in head - version MedDRA\23.0. | Coder Import (b) (4) | 15 Apr 2021 11:58:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 15 Apr 2021 11:58:11 |
| Data point term sent to Coder | System | 12 Apr 2021 20:13:52 |
| User entered 'mental foginess' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '20 Aug 2020' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 16 Apr 2021 17:22:21 |
| Query 'Data is required. Please provide.' answered with 'unknown time' (Site from System). | Jill York (b) (4) | 12 Apr 2021 20:13:33 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Apr 2021 20:13:23 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User entered empty. | System | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | (b) (4) System | 12 Apr 2021 20:13:49 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 12 Apr 2021 20:13:49 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 12 Apr 2021 20:13:23 |
| User entered '29 Aug 2020' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 16 Apr 2021 17:22:24 |
| Query 'Data is required. Please provide.' answered with 'unknown time' (Site from System). | Jill York (b) (4) | 12 Apr 2021 20:14:07 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 12 Apr 2021 20:13:23 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User entered empty. | System | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Severity](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Related (RELATED)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Not Related (NOT RELATED)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'None (NONE)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'I' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '0' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:14:00 |
| User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:13:49 |
| User entered 'Unknown (UNKNOWN)' | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

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 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System). | (b) (4) | 12 Apr 2021 20:14:00 |
| User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System). | System | 12 Apr 2021 20:13:49 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered empty. | Jill York (b) (4) | 12 Apr 2021 20:13:23 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User entered '0' | System | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |
| User entered '0' | System | 12 Apr 2021 20:13:23 |

US3142243

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:32

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 09:10:47 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 11:39:48 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Per Diary Dose 1 Day 8 Underarm Gland Swelling or Tenderness Response = Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity, however, there is no medication recorded in CM ecrf with this indication within this timeframe. Please review and update ecrf as appropriate. Else, provide clarification.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 22:40:48 |
| User closed query 'Per DM CLR: Per Diary Dose 1 Day 7, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). | | 07 Apr 2021 22:40:45 |
| Query 'Per DM CLR: Per Diary Dose 1 Day 7, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject was contacted and claims they do not remember what medication they took on this day ' (Site from DM). | Jill York (b) (4) | 07 Apr 2021 19:31:13 |
| Query 'Per DM CLR: Per Diary Dose 1 Day 8 Underarm Gland Swelling or Tenderness Response = Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity, however, there is no medication recorded in CM ecrf with this indication within this timeframe. Please review and update ecrf as appropriate. Else, provide clarification.' answered with 'subject was contacted and claims they do not remember what medication they took on this day ' (Site from DM). | Jill York (b) (4) | 07 Apr 2021 19:30:40 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|---|--------------------------------|----------------------|
| User opened query 'Per DM CLR: Per Diary Dose 1 Day 8 Underarm Gland Swelling or Tenderness Response = Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity, however, there is no medication recorded in CM ecrf with this indication within this timeframe. Please review and update ecrf as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 04:57:56 |
| User opened query 'Per DM CLR: Per Diary Dose 1 Day 7, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). | | 13 Jan 2021 11:15:39 |
| User entered 'Yes (Y)' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:03:56 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 05 Sep 2020 09:26:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Sep 2020 09:26:52 |
| Data point term sent to Coder | System | 04 Sep 2020 16:06:55 |
| User entered 'progesterone' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:06:35 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'menopausal' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Oct 2020 16:50:55 |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'actual dose was not specified ' (Site from DM). | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:28:55 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 06:40:25 |
| User entered '2' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:06:35 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'tablet (TABLET)' | (b) (4) Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:06:35 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'UN UNK 2019' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:06:35 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:06:35 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:06:35 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 04 Sep 2020 16:06:35 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Sep 2020 16:11:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Sep 2020 16:11:51 |
| Data point term sent to Coder | System | 04 Sep 2020 16:10:04 |
| User entered 'Estradiol' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'menopausal' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Oct 2020 16:51:02 |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'actual does was not specified ' (Site from DM). | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:29:08 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 06:40:11 |
| User entered '1' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:09:46 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'UN UNK 2019' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:09:46 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:09:46 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:09:46 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 04 Sep 2020 16:09:46 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 04 Sep 2020 16:25:40 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 16:25:40 |
| Data point term sent to Coder | System | 04 Sep 2020 16:24:47 |
| Data point term sent to Coder | System | 04 Sep 2020 16:23:45 |
| User entered 'trazodone ' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:23:33 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'insomnia' | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '50' | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'mg (mg)' | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'once daily (QD)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 16:23:46 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 04 Sep 2020 16:23:46 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error | Meghan York (b) (4) | 04 Sep 2020 16:23:46 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 16:23:33 |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2015). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Oct 2020 16:51:15 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2015). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'updated ' (Site from DM). | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:29:24 |
| User entered 'UN UNK 2015' reason for change: Data Entry Error | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:29:18 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2015). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 06:40:37 |
| User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 04 Sep 2020 16:24:12 |
| User entered 'UN UNK 2010' reason for change: Data Entry Error | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:24:12 |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 04 Sep 2020 16:23:33 |
| User entered empty. | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:23:33 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 16:24:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 04 Sep 2020 16:24:12 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Meghan York (b) (4) | 04 Sep 2020 16:24:12 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 16:23:33 |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 16:24:12 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 04 Sep 2020 16:24:12 |
| User entered 'No (N)' reason for change: Data Entry Error | Meghan York (b) (4) | 04 Sep 2020 16:24:12 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 16:23:33 |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:23:33 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:23:33 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:23:33 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 04 Sep 2020 16:23:33 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 04 Sep 2020 16:26:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 04 Sep 2020 16:26:49 |
| Data point term sent to Coder | System | 04 Sep 2020 16:25:50 |
| User entered 'xanax' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:25:36 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'insomnia' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4) | |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated ' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 16:51:23 |
| User entered '0.5' reason for change: Data Entry Error | Meghan York (b) (4) | 19 Oct 2020 20:30:02 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). | (b) (4) | |
| User entered '50' | Meghan York (b) (4) | 19 Oct 2020 20:29:55 |
| | (b) (4) | |
| | (b) (4), (b) (6) | 05 Oct 2020 06:41:00 |
| | | |
| | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'mg (mg)' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Frequency](#)

| Audit | User | Time (GMT) |
|---------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'every month (QM)' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 23 Oct 2020 16:51:55 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2015). Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'date is now correct on med history page ' (Site from DM). | Meghan York (b) (4) (b) (4) | 19 Oct 2020 20:31:07 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2015). Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 06:41:06 |
| User entered 'UN UNK 1985' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:25:36 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Meghan York (b) (4) | 04 Sep 2020 16:25:47 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System). | | 04 Sep 2020 16:25:47 |
| User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System). | | 04 Sep 2020 16:25:36 |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:25:36 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:25:36 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Sep 2020 16:25:36 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '802 (802)' | System | 04 Sep 2020 16:25:36 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 27 Oct 2020 20:30:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 27 Oct 2020 20:30:28 |
| Data point term sent to Coder | System | 27 Oct 2020 20:29:06 |
| Coding entries removed. | Meghan York (b) (4) | 27 Oct 2020 20:29:04 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 04 Sep 2020 16:30:07 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 04 Sep 2020 16:30:07 |
| Data point term sent to Coder | System | 04 Sep 2020 16:26:51 |
| User entered 'xyzal' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 02 Nov 2020 09:57:51 |
| Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'done' (Site from DM). | Meghan York (b) (4) (b) (4) | 27 Oct 2020 20:29:12 |
| User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error | Meghan York (b) (4) (b) (4) | 27 Oct 2020 20:29:04 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 24 Oct 2020 05:59:09 |
| Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM). | | 24 Oct 2020 05:59:03 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | | 24 Oct 2020 05:58:57 |
| User entered 'allergies' | Meghan York (b) (4) (b) (4) | 04 Sep 2020 16:26:45 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '1' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'tablet (TABLET)' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'Oral (ORAL)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:26:45 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'UN UNK 2013' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered '0' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered empty. | Meghan York (b) (4) | 04 Sep 2020 16:26:45 |
| | (b) (4) | |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'No (N)' | (b) (4) Meghan York (b) (4) | 04 Sep 2020 16:26:45 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 16:26:45 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 16:26:45 |

US3142243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:32

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 16:26:45 |

US3142243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:03:32

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| | (b) (4) | |
| User entered 'No (N)' | Jami Wagner (b) (4) | 18 Mar 2021 21:13:23 |
| | (b) (4) | |

US3142243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:03:32

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:10:36 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered '19 Aug 2020' | (b) (4) Shelby Pickle (b) (4) | 15 Jan 2021 16:56:47 |

US3142243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:03:32

[Primary reason for dosing discontinuation](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:10:36 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User entered 'AE (specify) (ADVERSE EVENT)' | (b) (4) Shelby Pickle (b) (4) | 15 Jan 2021 16:56:47 |

US3142243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 23:10:36 |
| User signature succeeded. | Ripley Hollister (b) (4) | 18 Apr 2021 21:37:57 |
| User closed query 'Per CDM-RQ: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM). | (b) (4), (b) (6) | 16 Apr 2021 17:12:32 |
| Query 'Per CDM-RQ: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' answered with 'UPDATED' (Site from DM). | Jill York (b) (4) | 12 Apr 2021 20:22:54 |
| User entered 'LEFT ARMPIT SWELLING AE#3 FATIGUE AE#1 SITE INJECTION PAIN #3' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:21:29 |
| User entered 'left armpit swelling' reason for change: Data Entry Error | Jill York (b) (4) | 12 Apr 2021 20:19:19 |
| User opened query 'Per CDM-RQ: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 09:36:40 |
| User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '# symbol and 'AE logline number'. Please consider updating AE specify field to include only the '# symbol and 'AE logline number' (i.e. #1 for row 1).' (Site from DM). | | 07 Apr 2021 09:36:04 |

US3142243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:03:32

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

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'will update' (Site from DM). | Jill York (b) (4) | 06 Apr 2021 19:30:29 |
| User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM). | (b) (4), (b) (6) | 13 Mar 2021 15:26:10 |
| Query 'Per CDM: Per sponsor review, please update specify field to include AE, number sign, and number. (i.e. AE #1).' canceled (Site from DM). | (b) (4), (b) (6) | 13 Mar 2021 15:25:45 |
| User opened query 'Per CDM: Per sponsor review, please update specify field to include AE, number sign, and number. (i.e. AE #1).' (Site from DM). | | 02 Mar 2021 19:18:38 |
| User entered 'Reaction to the First Dose' | Shelby Pickle (b) (4) (b) (4) | 15 Jan 2021 16:56:47 |