

US3022193 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:43:06

All time stamps listed in this document are displayed in GMT

US3022193

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:06

[Participant ID](#)

US3022193

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

US3022193

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 20 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

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1950 |
| Age | 70 |
| Age Units | YEARS |
| Age (Derived) | 70 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 20 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

Generated On: 26 Nov 2020 08:43:06

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

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:06

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Condition | HYPOTHYROIDISM |
| Start date (dd MMM yyyy) | UN UNK 1980 |
| 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 1980 |
| Start Year (derived) | 1980 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Condition | OSTEOPENIA |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| 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 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 10:51 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 10:51 |
| Height (<i>xxx.x</i>) | 170.5 cm |
| Weight (<i>xxx.x</i>) | 52.5 kg |
| BMI (<i>xxx.x</i>) | 18.05970 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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

Generated On: 26 Nov 2020 08:43:06

| | |
|--|---|
| Date of assessment (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Is the participant of childbearing potential? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If No, what is the reason? | Surgically sterile <input type="radio"/> |
| | Post-menopausal <input checked="" type="radio"/> |
| | Partner medically sterile <input type="radio"/> |
| | Not reached age of Menarche <input type="radio"/> |
| | Other <input type="radio"/> |
| If Partner medically sterile or Other, specify _____ | |
| If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____ | |
| Date of surgery unknown | False |
| If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>) | UN UNK 2000 |
| Date of last menstruation unknown | False |

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

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

KNITTING CLUB, SHOPPING,
OUT TO EAT

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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| | |
|--|---|
| Resides in high density housing (e.g., high rise apartments with shared entrances or elevators) | False |
| Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| Resides in a single family home (i.e., detached housing) | True |
| Other | True |
| Specify | LIVES IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION |

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 20 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

Generated On: 26 Nov 2020 08:43:06

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187267

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

Generated On: 26 Nov 2020 08:43:06

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

| | |
|-------------------------------------|--|
| 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) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:51 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 10:51 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 130 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

| | |
|-------------------------------------|--|
| 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) | 20 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:59 (24 HR) |
| Vital Signs Date and Time (derived) | 20 AUG 2020 12:59 |
| Temperature (xxx.x) | 35.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 122 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 12:28 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 12:28

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

Generated On: 26 Nov 2020 08:43:06

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 20 AUG 2020 |
| Collection time (<i>00:00-23:59</i>) | 11:47 (24 HR) |
| Collection date and time (derived) | 20 AUG 2020 11:47 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:06

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 20 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (<i>00:00 - 23:59</i>) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:31 | 20 AUG 2020 11:31 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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: 26 Nov 2020 08:43:06

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 20 AUG 2020 13:01

PC Open Date & Time 20 AUG 2020 12:48

PC Close Date & Time 20 AUG 2020 15:18

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 20 AUG 2020 18:34 |
| PC Open Date & Time | 20 AUG 2020 16:13 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

97.2 °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

21 AUG 2020 18:35

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:30

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 18:31

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 19:16

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 22:17

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:36

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 13:01

PC Open Date & Time

20 AUG 2020 12:48

PC Close Date & Time

20 AUG 2020 15:18

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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 18:35

PC Open Date & Time

20 AUG 2020 16:13

PC Close Date & Time

21 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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)

2

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 18:36

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 18:31

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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 18:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

24 AUG 2020 19:16

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

25 AUG 2020 22:18

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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 17:37

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 13:02 |
| PC Open Date & Time | 20 AUG 2020 12:48 |
| PC Close Date & Time | 20 AUG 2020 15:18 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 20 AUG 2020 18:37 |
| PC Open Date & Time | 20 AUG 2020 16:13 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

| | | |
|----------------------|-------------------|------------------------------|
| | | Yes <input type="checkbox"/> |
| PC Time stamp | 21 AUG 2020 18:37 | |
| PC Open Date & Time | 21 AUG 2020 12:00 | |
| PC Close Date & Time | 22 AUG 2020 11:59 | |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

| | | |
|----------------------|-------------------|------------------------------|
| | | Yes <input type="checkbox"/> |
| PC Time stamp | 22 AUG 2020 18:32 | |
| PC Open Date & Time | 22 AUG 2020 12:00 | |
| PC Close Date & Time | 23 AUG 2020 11:59 | |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 AUG 2020 18:32 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 19:17 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 AUG 2020 22:18 |
| PC Open Date & Time | 25 AUG 2020 12:00 |
| PC Close Date & Time | 26 AUG 2020 11:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 AUG 2020 17:37 |
| PC Open Date & Time | 26 AUG 2020 12:00 |
| PC Close Date & Time | 27 AUG 2020 11:59 |

US3022193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022193

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 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 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

| | |
|-------------------------------------|---|
| 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) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:18 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 10:18 |
| Temperature (xxx.x) | 37.2 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 60 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 82 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

| | |
|-------------------------------------|--|
| 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) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:55 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 11:55 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 110 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

| | |
|--|--|
| Was study treatment given? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, reason not given | Participant declined due to Adverse Event <input type="radio"/> |
| | Physician withheld dose due to Adverse Event <input type="radio"/> |
| | Death <input type="radio"/> |
| | Lost To Follow-Up <input type="radio"/> |
| | Physician Decision <input type="radio"/> |
| | Pregnancy <input type="radio"/> |
| | Protocol Deviation <input type="radio"/> |
| | Study Terminated by Sponsor <input type="radio"/> |
| | Withdrawal of Consent by Participant <input type="radio"/> |
| | Confirmed COVID-19 <input type="radio"/> |
| | Other <input type="radio"/> |
| 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) | 17 SEP 2020 |
| What was the treatment time? (00:00-23:59) | 11:24 (24 HR) |
| Treatment Date and Time (derived) | 17 SEP 2020 11:24 |
| Which arm was used to give treatment? | Left Arm <input checked="" type="radio"/> |
| | Right Arm <input type="radio"/> |
| What was the frequency of the study treatment dosing? | ONCE |
| What was the route of administration for the study treatment? | INTRAMUSCULAR |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 17 SEP 2020 |
| Collection time (<i>00:00-23:59</i>) | 10:47 (24 HR) |
| Collection date and time (derived) | 17 SEP 2020 10:47 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:06

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 17 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (<i>00:00 - 23:59</i>) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:39 | 17 SEP 2020 10:39 |
| Nasopharyngeal Swab 2 | No | | |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

98.0 °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

17 SEP 2020 12:00

PC Open Date & Time

17 SEP 2020 11:44

PC Close Date & Time

17 SEP 2020 14:14

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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 98.3 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 17 SEP 2020 17:03 |
| PC Open Date & Time | 17 SEP 2020 15:09 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °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

18 SEP 2020 16:37

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 18:25

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 18:52

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 17:55

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

98.2 °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

22 SEP 2020 21:52

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

98.2 °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

24 SEP 2020 07:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

17 SEP 2020 12:01

PC Open Date & Time

17 SEP 2020 11:44

PC Close Date & Time

17 SEP 2020 14:14

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

17 SEP 2020 17:04

PC Open Date & Time

17 SEP 2020 15:09

PC Close Date & Time

18 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 16:37

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 18:26

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

20 SEP 2020 18:52

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

21 SEP 2020 17:56

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

22 SEP 2020 21:52

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

24 SEP 2020 07:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 12:01 |
| PC Open Date & Time | 17 SEP 2020 11:44 |
| PC Close Date & Time | 17 SEP 2020 14:14 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 17 SEP 2020 17:05 |
| PC Open Date & Time | 17 SEP 2020 15:09 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 16:38 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 18:26 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 18:53 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 SEP 2020 17:56 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 21:53 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

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 ☒

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 SEP 2020 07:07 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3022193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022193

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022193

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022193

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 12 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 12 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 09:25 (24 HR) |
| Vital Signs Date and Time (derived) | 12 OCT 2020 09:25 |
| Temperature (<i>xxx.x</i>) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 110 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3022193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 12 OCT 2020 |
| Collection time (<i>00:00-23:59</i>) | 09:35 (24 HR) |
| Collection date and time (derived) | 12 OCT 2020 09:35 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| 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 14:50:16 |
| Patient Cloud Open Date & Time | 20 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 24 OCT 2020 23:59 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

27 OCT 2020 05:19:03

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

03 NOV 2020 05:54:59

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 04:17:39

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 61 |
|---|--|
| Have 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 68 |
|---|--|
| Have 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 24 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 28 OCT 2020 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 75 |
|---|--|
| Have 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 82 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 89 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 14 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 18 NOV 2020 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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 <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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 16 DEC 2020 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 19 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 23 DEC 2020 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 131 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 30 DEC 2020 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 145 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 152 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 166 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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 <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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 222 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 31 MAR 2021 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 229 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| TIMEPOINT | DAY 243 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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 <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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 264

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

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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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

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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](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐
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 ☐

US3022193

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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 | 03 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 07 JUL 2021 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐
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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 509

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 29 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 02 FEB 2022 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 593

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

| | |
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| Patient Cloud Open Date & Time | 02 APR 2022 00:01 |
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|---|-------------------|
| Patient Cloud Close Date & Time | 06 APR 2022 23:59 |
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US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐
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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 20 APR 2022 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐
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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 2022 00:01 |
| Patient Cloud Close Date & Time | 29 JUN 2022 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 684

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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="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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 2022 00:01 |
| Patient Cloud Close Date & Time | 07 SEP 2022 23:59 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐
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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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 ☐
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 ☐

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

| 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"/> |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3022193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022193

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022193

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:43:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022193

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

| | |
|--|--|
| AEID | USA-US051-2020-MRNA-1273-P30 1000007 |
| Adverse event | OVARIAN CYSTS (RIGHT) |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 17 SEP 2020 |
| Start time (00:00-23:59) | 05:00 (24 HR) |
| AE start date and time (derived) | 17 SEP 2020 05:00 |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 07 OCT 2020 |
| End time (00:00-23:59) | 11:00 (24 HR) |
| AE End Date and Time (derived) | 07 OCT 2020 11:00 |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 06 OCT 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 07 OCT 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

v6.020 DTW (1102)

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US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

| | |
|--|--|
| AEID | |
| Adverse event | ATOPIC DERMATITIS |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 06 OCT 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) | 13 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| v6.020 DTW (1102) | 340 of 1691 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

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

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:06

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

Yes ☒

No ☐

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

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

| | |
|--------------------------------|--|
| Name of Medication | LEVOTHYROXINE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | HYPOTHYROIDISM |
| Dose per administration | 50 |
| Dose unit | mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

| | |
|--|--------------------------------------|
| 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 1980 |
| 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"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

| | |
|--------------------------------------|---|
| Name of Medication | ALENDRONATE |
| Prophylaxis | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Indication | OSTEOPENIA |
| Dose per administration | 70 |
| Dose unit | mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input checked="" type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

| | | |
|--|--------------------------|----------------------------------|
| | 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 2010 |
| 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 checked="" type="radio"/> |
| | 804 | <input type="radio"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

| | |
|--------------------------------------|--|
| Name of Medication | ACETAMINOPHEN |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | HEADACHE PAIN |
| Dose per administration | 325 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

| | | |
|---|--------------------------|----------------------------------|
| | 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"/> |
| <hr/> | | |
| If route of administration is Other, specify <input type="text"/> | | |
| <hr/> | | |
| Start date (dd MMM yyyy) | UN | UNK 2015 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/> | | |
| <hr/> | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| <hr/> | | |
| Separate Dosage Number (derived) | <input type="text"/> | |
| Interval Dosage Unit Number (derived) | <input type="text"/> | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

| | |
|--------------------------------|--|
| Name of Medication | OXYCODONE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | OVARIAN CYSTS |
| Dose per administration | 325 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 06 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 10 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

| | |
|--------------------------------|--|
| Name of Medication | IBUPROFEN |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | OVARIAN CYSTS |
| Dose per administration | 800 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify | |
| Frequency | once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

| | | |
|--|--------------------------|-------------------------------------|
| | 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"/> |
| <hr/> | | |
| If route of administration is Other, specify <hr/> | | |
| Start date (dd MMM yyyy) | | 06 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) | | 08 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| <hr/> | | |
| Separate Dosage Number (derived) | <hr/> | |
| Interval Dosage Unit Number (derived) | <hr/> | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

| | |
|--------------------------------------|--|
| Name of Medication | DOCUSATE SODIUM |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | OVARIAN CYSTS |
| Dose per administration | 100 |
| Dose unit | mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/> |
| If dose unit is Other, specify _____ | |
| Frequency | once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/> |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

| | | |
|---|--------------------------|-------------------------------------|
| | 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"/> |
| <hr/> | | |
| If route of administration is Other, specify <input type="text"/> | | |
| <hr/> | | |
| Start date (dd MMM yyyy) | | 06 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) | | 10 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| <hr/> | | |
| Separate Dosage Number (derived) | | 2 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3022193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:43:06

| Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 06 OCT 2020 | HYSTERECTOMY | Adverse Event | |

US3022193

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:06

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3022193

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:43:06

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 ☐

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

| | |
|--|---|
| SAEID | USA-US051-2020-MRNA-1273-P301000007 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | PAUL |
| Investigator's Last Name | BRADLEY |
| Site Address: Street | 340 EISENHOWER DR. |
| Site Address: City | SAVANNAH |
| Site Address: State | GA |
| Site Address: Postal Code | 31406 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:06

| | |
|---|---|
| SAEID | USA-US051-2020-MRNA-1273-P301000007 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | PAUL |
| Investigator's Last Name | BRADLEY |
| Site Address: Street | 340 EISENHOWER DR. |
| Site Address: City | SAVANNAH |
| Site Address: State | GA |
| Site Address: Postal Code | 31406 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 09/OCT/2020 16:48 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:06

| | |
|---|---|
| SAEID | USA-US051-2020-MRNA-1273-P301000007 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | PAUL |
| Investigator's Last Name | BRADLEY |
| Site Address: Street | 340 EISENHOWER DR. |
| Site Address: City | SAVANNAH |
| Site Address: State | GA |
| Site Address: Postal Code | 31406 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 23/OCT/2020 20:37 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3022193 (Prod: Meridian Clinical Research)

US3022193

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:06

[Participant ID](#)

| Audit | User | Time (GMT) |
|--------------------------|---|----------------------|
| User entered 'US3022193' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 20 Aug 2020 15:04:49 |

US3022193

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:12 |

US3022193

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User entered '20 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 20 Aug 2020 15:04:50 |

US3022193

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:12 |

US3022193

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 20 Aug 2020 17:07:12 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Date of Birth \(MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User entered (b) (6) 1950' | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 20 Aug 2020 15:04:51 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Age](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '70' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '70' | System | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User entered 'Female (F)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[White](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered 'I' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Black](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Asian](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Other](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:06

[Not reported](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:07:36 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '20 Aug 2020' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Aug 2020' | System | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2020' | System | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User entered 'Amendment 2 (2)' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:48:52 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------|--|----------------------|
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 20 Aug 2020 15:04:50 |

US3022193

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:06

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Aug 2020 16:49:14 |

US3022193

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:49:14 |

US3022193

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:06

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:07 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:11:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:11:29 |
| Data point term sent to Coder | System | 20 Aug 2020 17:10:18 |
| User entered 'hypothyroidism' | Stella Yoon (b) (4) | 20 Aug 2020 17:09:29 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 1980' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1980' | System | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1980' | System | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:09:29 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

Condition

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:11:31 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 20 Aug 2020 17:11:31 |
| Data point term sent to Coder | System | 20 Aug 2020 17:10:22 |
| User entered 'osteopenia' | Stella Yoon (b) (4) | 20 Aug 2020 17:09:44 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2010' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2010' | System | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2010' | System | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:09:44 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Nov 2020 16:39:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Nov 2020 16:39:36 |
| Data point term sent to Coder | System | 09 Nov 2020 16:39:16 |
| Coding entries removed. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:39:01 |
| User entered 'intermittent HEADACHE' reason for change: Data Entry Error | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:39:01 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:11:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:11:30 |
| Data point term sent to Coder | System | 20 Aug 2020 17:10:23 |
| User entered 'headache' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2000' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2000' | System | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:10:00 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

Condition

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Sep 2020 15:00:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | (b) (4) | 24 Sep 2020 15:00:54 |
| Data point term sent to Coder | System | 24 Sep 2020 14:59:12 |
| User entered 'post menopausal' | Shanice Bennett (b) (4) | 24 Sep 2020 14:58:28 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'un UNK 2000' | Shanice Bennett (b) (4) (b) (4) | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2000' | System | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2000' | System | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Sep 2020 14:58:28 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------|--------------------------------|----------------------|
| User entered '10:51' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 10:51' | System | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User entered '170.5' cm | Stella Yoon (b) (4) | 20 Aug 2020 17:11:01 |
| DataPoint set to visible. | (b) (4) System | 20 Aug 2020 16:49:14 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| User entered '52.5' kg | Stella Yoon (b) (4) | 20 Aug 2020 17:11:01 |
| DataPoint set to visible. | (b) (4) System | 20 Aug 2020 16:49:14 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: User entered '18.05970' | System | 17 Sep 2020 00:15:56 |
| User entered '18.1' | System | 20 Aug 2020 17:11:01 |
| DataPoint set to visible. | System | 20 Aug 2020 16:49:14 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'kg/m2' | System | 20 Aug 2020 17:11:01 |
| DataPoint set to visible. | System | 20 Aug 2020 16:49:14 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 13 Nov 2020 05:26:00 |
| Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM). | Morgan Deal (b) (4) (b) (4) | 12 Nov 2020 16:58:13 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) (b) (4) | 12 Nov 2020 16:58:07 |
| User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 10:29:11 |
| User entered '36.8' C | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| User entered empty; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:07 |
| User entered 'Oral (Oral)' | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:11:01 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:07 |
| User entered '67' | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:11:01 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:07 |
| User entered '16' | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:11:01 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:07 |
| User entered '130' | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:11:01 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:07 |
| User entered '80' | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:11:01 |
| | (b) (4) | |

US3022193

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 17:11:01 |

US3022193

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:08 |

US3022193

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:08 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

Is the participant of childbearing potential?

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

If No, what is the reason?

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM). | (b) (4), (b) (6) | 25 Sep 2020 18:46:15 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'updated' (Site from DM). | Shanice Bennett (b) (4) | 24 Sep 2020 14:58:34 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM). | (b) (4), (b) (6) | 08 Sep 2020 10:48:37 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | Stella Yoon (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

Date of surgery unknown

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'un UNK 2000' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:06

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:11:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Other

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

[Specify](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User entered 'knitting club, shopping, out to eat' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

No Risk Identified

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered 'I' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

Other

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered 'I' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:06

[Specify](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User entered 'lives in a community with ongoing person to person transmission' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:29 |

US3022193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:40 |

US3022193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:40 |

US3022193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:40 |

US3022193

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 20 Aug 2020 17:12:40 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| User entered '20 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 20 Aug 2020 15:59:44 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 05:51:14 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:51:13 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 20 Aug 2020 15:59:44 |
| User entered '187267' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 20 Aug 2020 15:59:44 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------------------|--|----------------------|
| User entered '>=65 years (3)' | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 20 Aug 2020 15:59:44 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:59 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:59 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:59 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:59 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

[Liver Disease](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:12:59 |

US3022193

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | (b) (4), (b) (6) | 13 Nov 2020 11:26:19 |
| Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM). | Morgan Deal (b) (4) | 12 Nov 2020 18:19:41 |
| User entered 'No (N)' | (b) (4) | 12 Nov 2020 18:19:35 |
| User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | Morgan Deal (b) (4), (b) (6) | 28 Oct 2020 16:59:01 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:36:51 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:43:47 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:06

Height

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 13 Nov 2020 06:35:39 |
| Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM). | Morgan Deal (b) (4) | 12 Nov 2020 16:59:05 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4) | 12 Nov 2020 16:58:59 |
| User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 10:11:32 |
| User entered '170.5' cm | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:06

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:59 |
| User entered '52.5' kg | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |
| | (b) (4) | |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:06

Height

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 13 Nov 2020 06:35:39 |
| Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM). | Morgan Deal (b) (4) | 12 Nov 2020 16:59:05 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4) | 12 Nov 2020 16:58:59 |
| User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 10:11:32 |
| User entered '170.5' cm | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:06

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:59 |
| User entered '52.5' kg | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |
| | (b) (4) | |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------|--------------------------------|----------------------|
| User entered '10:51' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 10:51' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered '36.8' C | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (Oral)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '67' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '16' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|--------------------------------|----------------------|
| User entered '130' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '80' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:06

Height

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 13 Nov 2020 06:35:39 |
| Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM). | Morgan Deal (b) (4) | 12 Nov 2020 16:59:05 |
| User entered missing code ND - Not Done; reason for change Per Query Resolution | (b) (4) | 12 Nov 2020 16:58:59 |
| User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 10:11:32 |
| User entered '170.5' cm | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:06

Weight

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Per Query Resolution | Morgan Deal (b) (4) | 12 Nov 2020 16:58:59 |
| User entered '52.5' kg | (b) (4) | |
| | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |
| | (b) (4) | |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version. | | 21 Aug 2020 05:51:11 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol, 30 minutes post dose' (Site from System). | Stella Yoon (b) (4) | 20 Aug 2020 17:14:59 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | (b) (4) | 20 Aug 2020 17:14:50 |
| User entered '12:59' | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |
| | (b) (4) | |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:59' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 25 Sep 2020 18:45:26 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' | Shanice Bennett (b) (4) | 24 Sep 2020 02:04:49 |
| answered with 'NCS' (Site from System). | (b) (4) | |
| Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 17 Sep 2020 00:15:56 |
| User entered '35.9' C | Stella Yoon (b) (4) | 20 Aug 2020 17:14:50 |
| | (b) (4) | |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (Oral)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '71' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '14' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|--------------------------------|----------------------|
| User entered '122' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '72' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 20 Aug 2020 17:14:50 |

US3022193

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Was the physical examination performed?

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:10 |

US3022193

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:10 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '20 Aug 2020' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------|------------------------------------|----------------------|
| User entered '12:28' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:28' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|------------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Shanice Bennett (b) (4) (b) (4) | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:29 |

US3022193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:29 |

US3022193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|--------------------------------|----------------------|
| User entered '11:47' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:29 |

US3022193

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:47' | System | 20 Aug 2020 17:15:29 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:06

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered '20 Aug 2020' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|--------------------------------|----------------------|
| User entered '11:31' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 11:31' | System | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:15:42 |

US3022193

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:46 |

US3022193

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Aug 2020 17:15:46 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:00:37', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'cd35e6cd-440a-4886-b330-93b5f94bbb73' | System | 20 Aug 2020 17:01:25 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 17:01:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:00:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'cd35e6cd-440a-4886-b330-93b5f94bbb73' | System | 20 Aug 2020 17:01:25 |
| User entered '96.7' | System | 20 Aug 2020 17:01:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:00:55', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'cd35e6cd-440a-4886-b330-93b5f94bbb73' | System | 20 Aug 2020 17:01:25 |
| User entered 'No (N)' | System | 20 Aug 2020 17:01:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:01:03', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'cd35e6cd-440a-4886-b330-93b5f94bbb73' | System | 20 Aug 2020 17:01:25 |
| User entered '20 Aug 2020 13:01' | System | 20 Aug 2020 17:01:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:48' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 15:18' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:33:58', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '9df6fd87-e11f-4b33-9656-ee13c9eac5c4' | System | 20 Aug 2020 22:34:30 |
| User entered 'Yes (Y)' | System | 20 Aug 2020 22:34:30 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:34:13', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '9df6fd87-e11f-4b33-9656-ee13c9eac5c4' | System | 20 Aug 2020 22:34:30 |
| User entered '97.5' | System | 20 Aug 2020 22:34:30 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:34:17', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '9df6fd87-e11f-4b33-9656-ee13c9eac5c4' | System | 20 Aug 2020 22:34:30 |
| User entered 'No (N)' | System | 20 Aug 2020 22:34:30 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:34:28', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '9df6fd87-e11f-4b33-9656-ee13c9eac5c4' | System | 20 Aug 2020 22:34:30 |
| User entered '20 Aug 2020 18:34' | System | 20 Aug 2020 22:34:30 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 16:13' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 2' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:34:50', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b0d51a05-f04b-4f1a-89ca-c2b2e811a3ab' | System | 21 Aug 2020 22:35:19 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 22:35:19 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:34:55', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b0d51a05-f04b-4f1a-89ca-c2b2e811a3ab' | System | 21 Aug 2020 22:35:19 |
| User entered '97.2' | System | 21 Aug 2020 22:35:19 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:35:01', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b0d51a05-f04b-4f1a-89ca-c2b2e811a3ab' | System | 21 Aug 2020 22:35:19 |
| User entered 'No (N)' | System | 21 Aug 2020 22:35:19 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:35:14', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b0d51a05-f04b-4f1a-89ca-c2b2e811a3ab' | System | 21 Aug 2020 22:35:19 |
| User entered '21 Aug 2020 18:35' | System | 21 Aug 2020 22:35:19 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 3' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:30:41', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '40fcf6d0-0739-4d31-b6f7-e5a7ee648ba8' | System | 22 Aug 2020 22:31:01 |
| User entered 'Yes (Y)' | System | 22 Aug 2020 22:31:01 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:30:47', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '40fcf6d0-0739-4d31-b6f7-e5a7ee648ba8' | System | 22 Aug 2020 22:31:01 |
| User entered '97.5' | System | 22 Aug 2020 22:31:01 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:30:51', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '40fcf6d0-0739-4d31-b6f7-e5a7ee648ba8' | System | 22 Aug 2020 22:31:01 |
| User entered 'No (N)' | System | 22 Aug 2020 22:31:01 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:30:58', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '40fcf6d0-0739-4d31-b6f7-e5a7ee648ba8' | System | 22 Aug 2020 22:31:01 |
| User entered '22 Aug 2020 18:30' | System | 22 Aug 2020 22:31:01 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 4' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:31:41', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'af430d9e-4423-430d-a5e2-d0c7893cb0ce' User entered 'Yes (Y)' | System | 23 Aug 2020 22:31:57 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:31:47', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'af430d9e-4423-430d-a5e2-d0c7893cb0ce' User entered '98.1' | System | 23 Aug 2020 22:31:57 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:31:50', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'af430d9e-4423-430d-a5e2-d0c7893cb0ce' | System | 23 Aug 2020 22:31:57 |
| User entered 'No (N)' | System | 23 Aug 2020 22:31:57 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:31:55', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'af430d9e-4423-430d-a5e2-d0c7893cb0ce' | System | 23 Aug 2020 22:31:57 |
| User entered '23 Aug 2020 18:31' | System | 23 Aug 2020 22:31:57 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 5' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:03', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73baee45-c3df-4a05-b433-9230ec84de0e' | System | 24 Aug 2020 23:16:25 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 23:16:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:10', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73baee45-c3df-4a05-b433-9230ec84de0e' User entered '97.3' | System | 24 Aug 2020 23:16:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:15', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73baee45-c3df-4a05-b433-9230ec84de0e' | System | 24 Aug 2020 23:16:25 |
| User entered 'No (N)' | System | 24 Aug 2020 23:16:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:21', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73baee45-c3df-4a05-b433-9230ec84de0e' | System | 24 Aug 2020 23:16:25 |
| User entered '24 Aug 2020 19:16' | System | 24 Aug 2020 23:16:25 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 6' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:17:39', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7e798797-5387-4208-9545-2514dc2ce450' | System | 26 Aug 2020 02:18:04 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 02:18:04 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:17:50', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7e798797-5387-4208-9545-2514dc2ce450' | System | 26 Aug 2020 02:18:04 |
| User entered '97.8' | System | 26 Aug 2020 02:18:04 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:17:54', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7e798797-5387-4208-9545-2514dc2ce450' | System | 26 Aug 2020 02:18:04 |
| User entered 'No (N)' | System | 26 Aug 2020 02:18:04 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:17:59', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7e798797-5387-4208-9545-2514dc2ce450' | System | 26 Aug 2020 02:18:04 |
| User entered '25 Aug 2020 22:17' | System | 26 Aug 2020 02:18:04 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 7' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:14', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96096aef-85db-4d2f-919d-502336702ce4' | System | 26 Aug 2020 21:36:35 |
| User entered 'Yes (Y)' | System | 26 Aug 2020 21:36:35 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:21', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96096aef-85db-4d2f-919d-502336702ce4' | System | 26 Aug 2020 21:36:35 |
| User entered '97.8' | System | 26 Aug 2020 21:36:35 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:26', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96096aef-85db-4d2f-919d-502336702ce4' | System | 26 Aug 2020 21:36:35 |
| User entered 'No (N)' | System | 26 Aug 2020 21:36:35 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:31', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96096aef-85db-4d2f-919d-502336702ce4' | System | 26 Aug 2020 21:36:35 |
| User entered '26 Aug 2020 17:36' | System | 26 Aug 2020 21:36:35 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:01:27', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c0ed5d74-483d-4a9f-82f8-f92bfb392d4b' | System | 20 Aug 2020 17:02:03 |
| User entered 'None (1)' | System | 20 Aug 2020 17:02:03 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:01:33', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c0ed5d74-483d-4a9f-82f8-f92bfb392d4b' | System | 20 Aug 2020 17:02:03 |
| User entered 'No (N)' | System | 20 Aug 2020 17:02:03 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:01:36', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c0ed5d74-483d-4a9f-82f8-f92bfb392d4b' | System | 20 Aug 2020 17:02:03 |
| User entered 'No (N)' | System | 20 Aug 2020 17:02:03 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:01:50', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c0ed5d74-483d-4a9f-82f8-f92bfb392d4b' | System | 20 Aug 2020 17:02:03 |
| User entered 'None (1)' | System | 20 Aug 2020 17:02:03 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:01:57', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c0ed5d74-483d-4a9f-82f8-f92bfb392d4b' User entered '20 Aug 2020 13:01' | System | 20 Aug 2020 17:02:03 |
| | System | 20 Aug 2020 17:02:03 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:48' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 15:18' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:34:58', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bf760ca1-6aa2-4ed0-a539-ae9c03d43c9' | System | 20 Aug 2020 22:35:53 |
| User entered 'Does not interfere with activity (2)' | System | 20 Aug 2020 22:35:53 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:35:19', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bf760ca1-6aa2-4ed0-a539-ae9c03d43c9' | System | 20 Aug 2020 22:35:53 |
| User entered 'No (N)' | System | 20 Aug 2020 22:35:53 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:35:22', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bf760ca1-6aa2-4ed0-a539-ae9c03d43c9' | System | 20 Aug 2020 22:35:53 |
| User entered 'No (N)' | System | 20 Aug 2020 22:35:53 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:35:39', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bf760ca1-6aa2-4ed0-a539-ae9c03d43c9' | System | 20 Aug 2020 22:35:53 |
| User entered 'None (1)' | System | 20 Aug 2020 22:35:53 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:35:51', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bf760ca1-6aa2-4ed0-a539-aee9c03d43c9' | System | 20 Aug 2020 22:35:53 |
| User entered '20 Aug 2020 18:35' | System | 20 Aug 2020 22:35:53 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 16:13' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 2' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:35:27', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60f62c18-4d3a-41d1-adcf-1f43abb9542e' | System | 21 Aug 2020 22:36:26 |
| User entered 'Does not interfere with activity (2)' | System | 21 Aug 2020 22:36:26 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:35:31', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60f62c18-4d3a-41d1-adcf-1f43abb9542e' | System | 21 Aug 2020 22:36:26 |
| User entered 'No (N)' | System | 21 Aug 2020 22:36:26 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:35:54', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60f62c18-4d3a-41d1-adcf-1f43abb9542e' User entered 'Yes (Y)' | System | 21 Aug 2020 22:36:26 |
| | System | 21 Aug 2020 22:36:26 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:06', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60f62c18-4d3a-41d1-adcf-1f43abb9542e' User entered '2' | System | 21 Aug 2020 22:36:26 |
| | System | 21 Aug 2020 22:36:26 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:15', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60f62c18-4d3a-41d1-adcf-1f43abb9542e' | System | 21 Aug 2020 22:36:26 |
| User entered 'None (1)' | System | 21 Aug 2020 22:36:26 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60f62c18-4d3a-41d1-adcf-1f43abb9542e' User entered '21 Aug 2020 18:36' | System | 21 Aug 2020 22:36:26 |
| | System | 21 Aug 2020 22:36:26 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 3' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:05', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd08ab139-c767-453d-87f4-9fd5ed337094' | System | 22 Aug 2020 22:31:23 |
| User entered 'Does not interfere with activity (2)' | System | 22 Aug 2020 22:31:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:09', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd08ab139-c767-453d-87f4-9fd5ed337094' | System | 22 Aug 2020 22:31:23 |
| User entered 'No (N)' | System | 22 Aug 2020 22:31:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:13', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd08ab139-c767-453d-87f4-9fd5ed337094' | System | 22 Aug 2020 22:31:23 |
| User entered 'No (N)' | System | 22 Aug 2020 22:31:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:17', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd08ab139-c767-453d-87f4-9fd5ed337094' | System | 22 Aug 2020 22:31:23 |
| User entered 'None (1)' | System | 22 Aug 2020 22:31:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:21', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd08ab139-c767-453d-87f4-9fd5ed337094' | System | 22 Aug 2020 22:31:23 |
| User entered '22 Aug 2020 18:31' | System | 22 Aug 2020 22:31:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 4' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:04', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bfd56cd5-2377-432c-b50c-862316bb01ad' | System | 23 Aug 2020 22:32:23 |
| User entered 'None (1)' | System | 23 Aug 2020 22:32:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:08', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bfd56cd5-2377-432c-b50c-862316bb01ad' | System | 23 Aug 2020 22:32:23 |
| User entered 'No (N)' | System | 23 Aug 2020 22:32:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:12', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bfd56cd5-2377-432c-b50c-862316bb01ad' | System | 23 Aug 2020 22:32:23 |
| User entered 'No (N)' | System | 23 Aug 2020 22:32:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:16', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bfd56cd5-2377-432c-b50c-862316bb01ad' | System | 23 Aug 2020 22:32:23 |
| User entered 'None (1)' | System | 23 Aug 2020 22:32:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:21', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'bfd56cd5-2377-432c-b50c-862316bb01ad' User entered '23 Aug 2020 18:32' | System | 23 Aug 2020 22:32:23 |
| | System | 23 Aug 2020 22:32:23 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 5' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:26', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '515143a8-693d-4f47-b1bb-3ef2611bc0a9' | System | 24 Aug 2020 23:16:44 |
| User entered 'None (1)' | System | 24 Aug 2020 23:16:44 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:30', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '515143a8-693d-4f47-b1bb-3ef2611bc0a9' | System | 24 Aug 2020 23:16:44 |
| User entered 'No (N)' | System | 24 Aug 2020 23:16:44 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:34', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '515143a8-693d-4f47-b1bb-3ef2611bc0a9' | System | 24 Aug 2020 23:16:44 |
| User entered 'No (N)' | System | 24 Aug 2020 23:16:44 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:39', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '515143a8-693d-4f47-b1bb-3ef2611bc0a9' | System | 24 Aug 2020 23:16:44 |
| User entered 'None (1)' | System | 24 Aug 2020 23:16:44 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '515143a8-693d-4f47-b1bb-3ef2611bc0a9' | System | 24 Aug 2020 23:16:44 |
| User entered '24 Aug 2020 19:16' | System | 24 Aug 2020 23:16:44 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 6' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:05', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60e33522-6705-42db-ad1c-45e55433588f' | System | 26 Aug 2020 02:18:21 |
| User entered 'None (1)' | System | 26 Aug 2020 02:18:21 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:08', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60e33522-6705-42db-ad1c-45e55433588f' | System | 26 Aug 2020 02:18:21 |
| User entered 'No (N)' | System | 26 Aug 2020 02:18:21 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:12', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60e33522-6705-42db-ad1c-45e55433588f' | System | 26 Aug 2020 02:18:21 |
| User entered 'No (N)' | System | 26 Aug 2020 02:18:21 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:15', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60e33522-6705-42db-ad1c-45e55433588f' | System | 26 Aug 2020 02:18:21 |
| User entered 'None (1)' | System | 26 Aug 2020 02:18:21 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:19', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '60e33522-6705-42db-ad1c-45e55433588f' | System | 26 Aug 2020 02:18:21 |
| User entered '25 Aug 2020 22:18' | System | 26 Aug 2020 02:18:21 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 7' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:38', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '14196724-500b-4d49-b84b-ce9dfb2c067e' | System | 26 Aug 2020 21:37:06 |
| User entered 'None (1)' | System | 26 Aug 2020 21:37:06 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '14196724-500b-4d49-b84b-ce9dfb2c067e' | System | 26 Aug 2020 21:37:06 |
| User entered 'No (N)' | System | 26 Aug 2020 21:37:06 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:47', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '14196724-500b-4d49-b84b-ce9dfb2c067e' | System | 26 Aug 2020 21:37:06 |
| User entered 'No (N)' | System | 26 Aug 2020 21:37:06 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:36:55', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '14196724-500b-4d49-b84b-ce9dfb2c067e' | System | 26 Aug 2020 21:37:06 |
| User entered 'None (1)' | System | 26 Aug 2020 21:37:06 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:01', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '14196724-500b-4d49-b84b-ce9dfb2c067e' | System | 26 Aug 2020 21:37:06 |
| User entered '26 Aug 2020 17:37' | System | 26 Aug 2020 21:37:06 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:05', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered 'None (0)' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:09', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered 'None (0)' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:13', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered 'None (0)' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:16', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered 'None (0)' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:20', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered 'None (0)' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered 'None (0)' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:30', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered 'No (N)' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T13:02:45', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e4d93972-1b44-4739-8c18-227314023298' | System | 20 Aug 2020 17:02:47 |
| User entered '20 Aug 2020 13:02' | System | 20 Aug 2020 17:02:47 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 12:48' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 15:18' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 1, after vaccination (at home)' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:36:10', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered 'None (0)' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:36:20', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered 'Some interference with activity (2)' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:36:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered 'None (0)' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:36:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered 'None (0)' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:36:36', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered 'None (0)' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:36:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered 'None (0)' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:36:54', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered 'No (N)' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-20T18:37:09', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '48a6b9b1-72a1-420f-a00e-428fa57aeab5' | System | 20 Aug 2020 22:37:11 |
| User entered '20 Aug 2020 18:37' | System | 20 Aug 2020 22:37:11 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Aug 2020 16:13' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 2' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:34', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered 'None (0)' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:39', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered 'None (0)' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered 'None (0)' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:48', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered 'None (0)' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:52', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered 'None (0)' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:36:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered 'None (0)' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:37:01', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered 'No (N)' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-21T18:37:11', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '90ee3871-d657-41f5-810b-7e6fb91efa7d' | System | 21 Aug 2020 22:37:13 |
| User entered '21 Aug 2020 18:37' | System | 21 Aug 2020 22:37:13 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 3' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:34', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered 'None (0)' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:38', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered 'None (0)' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:41', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered 'None (0)' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:44', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered 'None (0)' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:47', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered 'None (0)' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:50', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered 'None (0)' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:31:53', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered 'No (N)' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-22T18:32:02', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '11c89866-b40f-47f9-ad4d-8baaf5d73d00' | System | 22 Aug 2020 22:32:05 |
| User entered '22 Aug 2020 18:32' | System | 22 Aug 2020 22:32:05 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 4' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:26', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered 'None (0)' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered 'None (0)' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:32', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered 'None (0)' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:34', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered 'None (0)' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:37', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered 'None (0)' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:40', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered 'None (0)' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered 'No (N)' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-23T18:32:46', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f0adf5e5-5397-4164-89bf-84d49bea2c7d' | System | 23 Aug 2020 22:32:50 |
| User entered '23 Aug 2020 18:32' | System | 23 Aug 2020 22:32:50 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 5' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered 'None (0)' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:52', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered 'None (0)' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered 'None (0)' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:16:59', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered 'None (0)' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:17:01', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered 'None (0)' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:17:04', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered 'None (0)' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:17:09', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered 'No (N)' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-24T19:17:13', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '41afb5d7-1f0d-4e53-9074-77ef05df28a2' | System | 24 Aug 2020 23:17:16 |
| User entered '24 Aug 2020 19:17' | System | 24 Aug 2020 23:17:16 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 6' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered 'None (0)' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:27', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered 'None (0)' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:30', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered 'None (0)' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:33', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered 'None (0)' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:37', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered 'None (0)' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:40', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered 'None (0)' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered 'No (N)' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-25T22:18:54', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '29414257-7441-4aa9-a64b-351722100a72' | System | 26 Aug 2020 02:18:59 |
| User entered '25 Aug 2020 22:18' | System | 26 Aug 2020 02:18:59 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 7' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:07', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered 'None (0)' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:10', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered 'None (0)' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:13', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered 'None (0)' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:16', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered 'None (0)' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:19', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered 'None (0)' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:22', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered 'None (0)' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:26', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered 'No (N)' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-08-26T17:37:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '8d2327c8-0f59-485b-a2b8-95c1af2925e3' | System | 26 Aug 2020 21:37:31 |
| User entered '26 Aug 2020 17:37' | System | 26 Aug 2020 21:37:31 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Aug 2020 12:00' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Aug 2020 11:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:57:31 |

US3022193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '27 Aug 2020' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:57:31 |

US3022193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:57:31 |

US3022193

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:57:31 |

US3022193

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:57:38 |

US3022193

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Sep 2020 15:57:38 |

US3022193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:04 |

US3022193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '03 Sep 2020' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:04 |

US3022193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:04 |

US3022193

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:04 |

US3022193

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:10 |

US3022193

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Sep 2020 15:58:10 |

US3022193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:40 |

US3022193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '10 Sep 2020' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:40 |

US3022193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:40 |

US3022193

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:40 |

US3022193

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:58:45 |

US3022193

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Sep 2020 15:58:45 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:31:32 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '17 Sep 2020' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:31:32 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User entered 'Clinic (Clinic)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:31:32 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 17 Sep 2020 19:31:32 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '17 Sep 2020' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------|------------------------------------|----------------------|
| User entered '10:18' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 10:18' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered '37.2' C | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (Oral)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------------------------|----------------------|
| User entered '60' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------|------------------------------------|----------------------|
| User entered '16' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------------------------|----------------------|
| User entered '118' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------------------------|----------------------|
| User entered '82' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:06

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Were vital signs assessed?

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '17 Sep 2020' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------|------------------------------------|----------------------|
| User entered '11:55' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:55' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered '36.7' C | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (Oral)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------------------------|----------------------|
| User entered '68' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------|------------------------------------|----------------------|
| User entered '12' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------------------------|----------------------|
| User entered '110' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------------------------|----------------------|
| User entered '78' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:06

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 17 Sep 2020 19:33:08 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Was the physical examination performed?

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:31:40 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '17 Sep 2020' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:31:40 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '17 Sep 2020' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------|-----------------------------------|----------------------|
| User entered '11:24' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:24' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | Chevon Roberts (b) (4) (b) (4) | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:06

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:29 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '17 Sep 2020' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:29 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------------------------|----------------------|
| User entered '10:47' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:29 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 10:47' | System | 17 Sep 2020 19:33:29 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:06

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '17 Sep 2020' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Shanice Bennett (b) (4) | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------------------------|----------------------|
| User entered '10:39' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 10:39' | System | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Shanice Bennett (b) (4) | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 17 Sep 2020 19:33:44 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 17 Sep 2020 19:33:48 |

US3022193

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 17 Sep 2020 19:33:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:00:22', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '936c001b-c794-4268-9d36-a3998adabf0b' | System | 17 Sep 2020 16:00:48 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 16:00:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:00:28', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '936c001b-c794-4268-9d36-a3998adabf0b' User entered '98.0' | System | 17 Sep 2020 16:00:48 |
| | System | 17 Sep 2020 16:00:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

Was any MEDICATION TAKEN today for pain or fever?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:00:33', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '936c001b-c794-4268-9d36-a3998adabf0b' | System | 17 Sep 2020 16:00:48 |
| User entered 'No (N)' | System | 17 Sep 2020 16:00:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:00:40', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '936c001b-c794-4268-9d36-a3998adabf0b' | System | 17 Sep 2020 16:00:48 |
| User entered '17 Sep 2020 12:00' | System | 17 Sep 2020 16:00:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:44' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 14:14' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:03:41', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73c0aed3-a7d6-4a2e-a29a-9bf852cee02d' | System | 17 Sep 2020 21:03:57 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 21:03:57 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:03:47', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73c0aed3-a7d6-4a2e-a29a-9bf852cee02d' User entered '98.3' | System | 17 Sep 2020 21:03:57 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:03:51', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73c0aed3-a7d6-4a2e-a29a-9bf852cee02d' | System | 17 Sep 2020 21:03:57 |
| User entered 'No (N)' | System | 17 Sep 2020 21:03:57 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:03:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '73c0aed3-a7d6-4a2e-a29a-9bf852cee02d' User entered '17 Sep 2020 17:03' | System | 17 Sep 2020 21:03:57 |
| | System | 17 Sep 2020 21:03:57 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 15:09' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 2' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:36:17', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7bac1e27-bf63-4f0f-8e68-92e9091e5500' | System | 18 Sep 2020 20:37:08 |
| User entered 'Yes (Y)' | System | 18 Sep 2020 20:37:08 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:36:52', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7bac1e27-bf63-4f0f-8e68-92e9091e5500' | System | 18 Sep 2020 20:37:08 |
| User entered '99.0' | System | 18 Sep 2020 20:37:08 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:36:57', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7bac1e27-bf63-4f0f-8e68-92e9091e5500' | System | 18 Sep 2020 20:37:08 |
| User entered 'No (N)' | System | 18 Sep 2020 20:37:08 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:01', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '7bac1e27-bf63-4f0f-8e68-92e9091e5500' | System | 18 Sep 2020 20:37:08 |
| User entered '18 Sep 2020 16:37' | System | 18 Sep 2020 20:37:08 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 3' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:24:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e3c8f163-22d5-45a7-b12d-98476e5dbdd2' | System | 19 Sep 2020 22:25:52 |
| User entered 'Yes (Y)' | System | 19 Sep 2020 22:25:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:25:40', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e3c8f163-22d5-45a7-b12d-98476e5dbdd2' | System | 19 Sep 2020 22:25:52 |
| User entered '98.4' | System | 19 Sep 2020 22:25:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:25:44', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e3c8f163-22d5-45a7-b12d-98476e5dbdd2' | System | 19 Sep 2020 22:25:52 |
| User entered 'No (N)' | System | 19 Sep 2020 22:25:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:25:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e3c8f163-22d5-45a7-b12d-98476e5dbdd2' | System | 19 Sep 2020 22:25:52 |
| User entered '19 Sep 2020 18:25' | System | 19 Sep 2020 22:25:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 4' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:51:39', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baddaf3-275e-4c04-a2da-83e8eeb517c3' | System | 20 Sep 2020 22:52:17 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 22:52:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:06', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baddaf3-275e-4c04-a2da-83e8eeb517c3' | System | 20 Sep 2020 22:52:17 |
| User entered '98.3' | System | 20 Sep 2020 22:52:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:10', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baddaf3-275e-4c04-a2da-83e8eeb517c3' | System | 20 Sep 2020 22:52:17 |
| User entered 'No (N)' | System | 20 Sep 2020 22:52:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:14', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baddaf3-275e-4c04-a2da-83e8eeb517c3' | System | 20 Sep 2020 22:52:17 |
| User entered '20 Sep 2020 18:52' | System | 20 Sep 2020 22:52:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 5' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:54:50', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '283825c0-e38a-4ce6-aa63-9b531d1f1ac4' | System | 21 Sep 2020 21:55:48 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 21:55:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:55:38', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '283825c0-e38a-4ce6-aa63-9b531d1f1ac4' | System | 21 Sep 2020 21:55:48 |
| User entered '98.4' | System | 21 Sep 2020 21:55:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:55:41', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '283825c0-e38a-4ce6-aa63-9b531d1f1ac4' | System | 21 Sep 2020 21:55:48 |
| User entered 'No (N)' | System | 21 Sep 2020 21:55:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:55:44', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '283825c0-e38a-4ce6-aa63-9b531d1f1ac4' | System | 21 Sep 2020 21:55:48 |
| User entered '21 Sep 2020 17:55' | System | 21 Sep 2020 21:55:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 6' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '454fd723-1b7c-4cb5-b835-31d6d605f6e5' | System | 23 Sep 2020 01:52:45 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 01:52:45 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:35', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '454fd723-1b7c-4cb5-b835-31d6d605f6e5' | System | 23 Sep 2020 01:52:45 |
| User entered '98.2' | System | 23 Sep 2020 01:52:45 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:38', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '454fd723-1b7c-4cb5-b835-31d6d605f6e5' | System | 23 Sep 2020 01:52:45 |
| User entered 'No (N)' | System | 23 Sep 2020 01:52:45 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:41', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '454fd723-1b7c-4cb5-b835-31d6d605f6e5' | System | 23 Sep 2020 01:52:45 |
| User entered '22 Sep 2020 21:52' | System | 23 Sep 2020 01:52:45 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 7' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:15', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '209100c2-db25-4249-b26f-2484bed6ac4f' | System | 24 Sep 2020 11:06:33 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 11:06:33 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

Please record your **TEMPERATURE in °F**

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:23', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '209100c2-db25-4249-b26f-2484bed6ac4f' User entered '98.2' | System | 24 Sep 2020 11:06:33 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:26', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '209100c2-db25-4249-b26f-2484bed6ac4f' | System | 24 Sep 2020 11:06:33 |
| User entered 'No (N)' | System | 24 Sep 2020 11:06:33 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '209100c2-db25-4249-b26f-2484bed6ac4f' User entered '24 Sep 2020 07:06' | System | 24 Sep 2020 11:06:33 |
| | System | 24 Sep 2020 11:06:33 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:00:52', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'da204453-f150-481d-a879-1453c099c08a' | System | 17 Sep 2020 16:01:50 |
| User entered 'None (1)' | System | 17 Sep 2020 16:01:50 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:00:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'da204453-f150-481d-a879-1453c099c08a' | System | 17 Sep 2020 16:01:50 |
| User entered 'No (N)' | System | 17 Sep 2020 16:01:50 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:00', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'da204453-f150-481d-a879-1453c099c08a' | System | 17 Sep 2020 16:01:50 |
| User entered 'No (N)' | System | 17 Sep 2020 16:01:50 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:04', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'da204453-f150-481d-a879-1453c099c08a' | System | 17 Sep 2020 16:01:50 |
| User entered 'None (1)' | System | 17 Sep 2020 16:01:50 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:08', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'da204453-f150-481d-a879-1453c099c08a' User entered '17 Sep 2020 12:01' | System | 17 Sep 2020 16:01:50 |
| | System | 17 Sep 2020 16:01:50 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:44' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 14:14' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:12', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '4032ac4b-9ac1-438d-8904-fc2725bd2b9c' | System | 17 Sep 2020 21:04:38 |
| User entered 'Does not interfere with activity (2)' | System | 17 Sep 2020 21:04:38 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:16', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '4032ac4b-9ac1-438d-8904-fc2725bd2b9c' | System | 17 Sep 2020 21:04:38 |
| User entered 'No (N)' | System | 17 Sep 2020 21:04:38 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:26', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '4032ac4b-9ac1-438d-8904-fc2725bd2b9c' | System | 17 Sep 2020 21:04:38 |
| User entered 'No (N)' | System | 17 Sep 2020 21:04:38 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '4032ac4b-9ac1-438d-8904-fc2725bd2b9c' | System | 17 Sep 2020 21:04:38 |
| User entered 'None (1)' | System | 17 Sep 2020 21:04:38 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:35', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '4032ac4b-9ac1-438d-8904-fc2725bd2b9c' User entered '17 Sep 2020 17:04' | System | 17 Sep 2020 21:04:38 |
| | System | 17 Sep 2020 21:04:38 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 15:09' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 2' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:10', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b167766d-b846-4901-ba4d-5e26d0e93c29' | System | 18 Sep 2020 20:37:31 |
| User entered 'Does not interfere with activity (2)' | System | 18 Sep 2020 20:37:31 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:14', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b167766d-b846-4901-ba4d-5e26d0e93c29' | System | 18 Sep 2020 20:37:31 |
| User entered 'No (N)' | System | 18 Sep 2020 20:37:31 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:17', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b167766d-b846-4901-ba4d-5e26d0e93c29' | System | 18 Sep 2020 20:37:31 |
| User entered 'No (N)' | System | 18 Sep 2020 20:37:31 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:25', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b167766d-b846-4901-ba4d-5e26d0e93c29' | System | 18 Sep 2020 20:37:31 |
| User entered 'None (1)' | System | 18 Sep 2020 20:37:31 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b167766d-b846-4901-ba4d-5e26d0e93c29' | System | 18 Sep 2020 20:37:31 |
| User entered '18 Sep 2020 16:37' | System | 18 Sep 2020 20:37:31 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 3' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:25:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e54732cc-d7dc-4b80-81c8-33aa42b36ceb' | System | 19 Sep 2020 22:26:15 |
| User entered 'Does not interfere with activity (2)' | System | 19 Sep 2020 22:26:15 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:25:59', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e54732cc-d7dc-4b80-81c8-33aa42b36ceb' | System | 19 Sep 2020 22:26:15 |
| User entered 'No (N)' | System | 19 Sep 2020 22:26:15 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:03', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e54732cc-d7dc-4b80-81c8-33aa42b36ceb' | System | 19 Sep 2020 22:26:15 |
| User entered 'No (N)' | System | 19 Sep 2020 22:26:15 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:07', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e54732cc-d7dc-4b80-81c8-33aa42b36ceb' User entered 'None (1)' | System | 19 Sep 2020 22:26:15 |
| | System | 19 Sep 2020 22:26:15 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:12', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'e54732cc-d7dc-4b80-81c8-33aa42b36ceb' User entered '19 Sep 2020 18:26' | System | 19 Sep 2020 22:26:15 |
| | System | 19 Sep 2020 22:26:15 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 4' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:21', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '16f18578-8a46-463a-a2d9-899939c76d7c' | System | 20 Sep 2020 22:52:36 |
| User entered 'None (1)' | System | 20 Sep 2020 22:52:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '16f18578-8a46-463a-a2d9-899939c76d7c' | System | 20 Sep 2020 22:52:36 |
| User entered 'No (N)' | System | 20 Sep 2020 22:52:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:27', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '16f18578-8a46-463a-a2d9-899939c76d7c' | System | 20 Sep 2020 22:52:36 |
| User entered 'No (N)' | System | 20 Sep 2020 22:52:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:31', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '16f18578-8a46-463a-a2d9-899939c76d7c' | System | 20 Sep 2020 22:52:36 |
| User entered 'None (1)' | System | 20 Sep 2020 22:52:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:35', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '16f18578-8a46-463a-a2d9-899939c76d7c' | System | 20 Sep 2020 22:52:36 |
| User entered '20 Sep 2020 18:52' | System | 20 Sep 2020 22:52:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 5' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:55:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'ea7ec103-76e2-4cc8-a919-4fd5624773b1' User entered 'None (1)' | System | 21 Sep 2020 21:56:04 |
| | System | 21 Sep 2020 21:56:04 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:55:52', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'ea7ec103-76e2-4cc8-a919-4fd5624773b1' | System | 21 Sep 2020 21:56:04 |
| User entered 'No (N)' | System | 21 Sep 2020 21:56:04 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:55:54', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'ea7ec103-76e2-4cc8-a919-4fd5624773b1' | System | 21 Sep 2020 21:56:04 |
| User entered 'No (N)' | System | 21 Sep 2020 21:56:04 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:55:57', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'ea7ec103-76e2-4cc8-a919-4fd5624773b1' | System | 21 Sep 2020 21:56:04 |
| User entered 'None (1)' | System | 21 Sep 2020 21:56:04 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:00', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'ea7ec103-76e2-4cc8-a919-4fd5624773b1' | System | 21 Sep 2020 21:56:04 |
| User entered '21 Sep 2020 17:56' | System | 21 Sep 2020 21:56:04 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 6' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:46', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baf84ef-ec82-4158-a239-28a3aa27cdea' | System | 23 Sep 2020 01:53:00 |
| User entered 'None (1)' | System | 23 Sep 2020 01:53:00 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baf84ef-ec82-4158-a239-28a3aa27cdea' | System | 23 Sep 2020 01:53:00 |
| User entered 'No (N)' | System | 23 Sep 2020 01:53:00 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:52', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baf84ef-ec82-4158-a239-28a3aa27cdea' | System | 23 Sep 2020 01:53:00 |
| User entered 'No (N)' | System | 23 Sep 2020 01:53:00 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:55', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baf84ef-ec82-4158-a239-28a3aa27cdea' | System | 23 Sep 2020 01:53:00 |
| User entered 'None (1)' | System | 23 Sep 2020 01:53:00 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:52:58', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '3baf84ef-ec82-4158-a239-28a3aa27cdea' | System | 23 Sep 2020 01:53:00 |
| User entered '22 Sep 2020 21:52' | System | 23 Sep 2020 01:53:00 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 7' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:34', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96553ab5-11b2-4f01-b27f-952641ea2121' | System | 24 Sep 2020 11:06:48 |
| User entered 'None (1)' | System | 24 Sep 2020 11:06:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:37', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96553ab5-11b2-4f01-b27f-952641ea2121' | System | 24 Sep 2020 11:06:48 |
| User entered 'No (N)' | System | 24 Sep 2020 11:06:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:40', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96553ab5-11b2-4f01-b27f-952641ea2121' | System | 24 Sep 2020 11:06:48 |
| User entered 'No (N)' | System | 24 Sep 2020 11:06:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

Please select one response below

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96553ab5-11b2-4f01-b27f-952641ea2121' | System | 24 Sep 2020 11:06:48 |
| User entered 'None (1)' | System | 24 Sep 2020 11:06:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:46', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '96553ab5-11b2-4f01-b27f-952641ea2121' | System | 24 Sep 2020 11:06:48 |
| User entered '24 Sep 2020 07:06' | System | 24 Sep 2020 11:06:48 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:13', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered 'None (0)' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:17', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered 'None (0)' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:20', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered 'None (0)' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered 'None (0)' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:27', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered 'None (0)' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:30', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered 'None (0)' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:34', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered 'No (N)' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T12:01:39', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'f25cab85-3b1d-4669-a977-68e049c37d9b' | System | 17 Sep 2020 16:02:52 |
| User entered '17 Sep 2020 12:01' | System | 17 Sep 2020 16:02:52 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 11:44' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 14:14' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 1, after vaccination (at home)' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:41', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered 'None (0)' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:45', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered 'None (0)' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered 'None (0)' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:53', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered 'None (0)' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:04:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered 'None (0)' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:05:00', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered 'None (0)' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:05:13', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered 'No (N)' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-17T17:05:16', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'db7f5a5e-d223-4ca2-bdab-48a3e0ee54a4' | System | 17 Sep 2020 21:05:20 |
| User entered '17 Sep 2020 17:05' | System | 17 Sep 2020 21:05:20 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '17 Sep 2020 15:09' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 2' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:38', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered 'None (0)' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:42', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered 'None (0)' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:44', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered 'None (0)' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:46', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered 'None (0)' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:37:53', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered 'None (0)' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:38:04', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered 'None (0)' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:38:19', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered 'No (N)' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-18T16:38:22', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '1e20c76b-680c-4486-b125-0f8d4e1d1b88' | System | 18 Sep 2020 20:38:24 |
| User entered '18 Sep 2020 16:38' | System | 18 Sep 2020 20:38:24 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 3' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:18', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered 'None (0)' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:21', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered 'None (0)' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered 'None (0)' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:27', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered 'None (0)' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:32', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered 'None (0)' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:35', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered 'None (0)' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:40', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered 'No (N)' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-19T18:26:44', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b61b1373-f395-40e2-bddc-b3e51efcf2af' | System | 19 Sep 2020 22:26:46 |
| User entered '19 Sep 2020 18:26' | System | 19 Sep 2020 22:26:46 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 4' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:40', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered 'None (0)' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered 'None (0)' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:46', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered 'None (0)' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:49', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered 'None (0)' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:51', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered 'None (0)' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:52:54', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered 'None (0)' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:53:01', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered 'No (N)' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-20T18:53:05', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'b7a0dee6-b071-46f5-8fb6-c467499b0a43' | System | 20 Sep 2020 22:53:07 |
| User entered '20 Sep 2020 18:53' | System | 20 Sep 2020 22:53:07 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '20 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 5' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:05', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' User entered 'None (0)' | System | 21 Sep 2020 21:56:36 |
| | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:08', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' User entered 'None (0)' | System | 21 Sep 2020 21:56:36 |
| | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:11', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' | System | 21 Sep 2020 21:56:36 |
| User entered 'None (0)' | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:14', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' | System | 21 Sep 2020 21:56:36 |
| User entered 'None (0)' | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:19', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' | System | 21 Sep 2020 21:56:36 |
| User entered 'None (0)' | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:21', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' | System | 21 Sep 2020 21:56:36 |
| User entered 'None (0)' | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:29', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' | System | 21 Sep 2020 21:56:36 |
| User entered 'No (N)' | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-21T17:56:31', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '604df750-7e20-4a3c-91a7-74fa694a2401' User entered '21 Sep 2020 17:56' | System | 21 Sep 2020 21:56:36 |
| | System | 21 Sep 2020 21:56:36 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '21 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 6' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:03', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered 'None (0)' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:06', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered 'None (0)' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:10', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered 'None (0)' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:12', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered 'None (0)' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:15', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered 'None (0)' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:18', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered 'None (0)' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:22', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered 'No (N)' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-22T21:53:26', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'd97cc005-ed06-429f-bfb8-999bf47ce7b3' | System | 23 Sep 2020 01:53:27 |
| User entered '22 Sep 2020 21:53' | System | 23 Sep 2020 01:53:27 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 17 Sep 2020 15:59:17 |
| User entered 'Day 7' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:50', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered 'None (0)' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:53', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered 'None (0)' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered 'None (0)' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:06:58', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered 'None (0)' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:07:01', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered 'None (0)' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:07:03', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered 'None (0)' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:07:07', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered 'No (N)' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-09-24T07:07:14', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'fb983cde-0f69-468f-840c-a95b0186f63b' | System | 24 Sep 2020 11:07:16 |
| User entered '24 Sep 2020 07:07' | System | 24 Sep 2020 11:07:16 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Sep 2020 12:00' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:06

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 11:59' | System | 17 Sep 2020 15:59:17 |

US3022193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 14:51:04 |

US3022193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 14:51:04 |

US3022193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 24 Sep 2020 14:51:04 |

US3022193

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 14:51:04 |

US3022193

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 14:50:54 |

US3022193

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Sep 2020 14:50:54 |

US3022193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 18:35:32 |

US3022193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '01 Oct 2020' | (b) (4), (b) (6) | 02 Oct 2020 18:35:32 |

US3022193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 02 Oct 2020 18:35:32 |

US3022193

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 02 Oct 2020 18:35:32 |

US3022193

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Oct 2020 18:35:39 |

US3022193

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 02 Oct 2020 18:35:39 |

US3022193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 14:27:50 |

US3022193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '08 Oct 2020' | (b) (4), (b) (6) | 09 Oct 2020 14:27:50 |

US3022193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 09 Oct 2020 14:27:50 |

US3022193

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 09 Oct 2020 14:27:50 |

US3022193

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 14:27:55 |

US3022193

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Oct 2020 14:27:55 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 17:05:27 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '12 Oct 2020' | (b) (4), (b) (6) | 12 Oct 2020 17:05:27 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 12 Oct 2020 17:05:27 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:06

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 12 Oct 2020 17:05:27 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '12 Oct 2020' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:25' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 09:25' | System | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered '36.8' C | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '70' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '14' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '110' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '73' | (b) (4), (b) (6) | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:06

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 12 Oct 2020 17:06:02 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Was the physical examination performed?

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 17:06:13 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:06

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '12 Oct 2020' | (b) (4), (b) (6) | 12 Oct 2020 17:06:13 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 17:06:28 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '12 Oct 2020' | (b) (4), (b) (6) | 12 Oct 2020 17:06:28 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:35' | (b) (4), (b) (6) | 12 Oct 2020 17:06:28 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '12 Oct 2020 09:35' | System | 12 Oct 2020 17:06:28 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Oct 2020 17:06:46 |

US3022193

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 12 Oct 2020 17:06:46 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 64' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[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 (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-10-22T14:49:56', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'a90ab580-b64a-44a1-963d-bf0a219fc66e' User entered 'No (N)' | System | 22 Oct 2020 18:50:18 |
| | System | 22 Oct 2020 18:50:18 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

Have you been exposed to someone with 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 (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-10-22T14:50:04', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'a90ab580-b64a-44a1-963d-bf0a219fc66e' | System | 22 Oct 2020 18:50:18 |
| User entered 'No (N)' | System | 22 Oct 2020 18:50:18 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57EB463D-E6FE-45E7-ACDB-7C36A820BA3B)', Time: '2020-10-22T14:50:16', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'a90ab580-b64a-44a1-963d-bf0a219fc66e' User entered '22 Oct 2020 14:50:16' | System | 22 Oct 2020 18:50:18 |
| | System | 22 Oct 2020 18:50:18 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '20 Oct 2020 00:01' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '24 Oct 2020 23:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 71' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[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 (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-10-27T05:18:43', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '05362a3b-aff3-4444-bcee-4adcfbde6ef6' | System | 27 Oct 2020 09:19:06 |
| User entered 'No (N)' | System | 27 Oct 2020 09:19:06 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Have you been exposed to someone with 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 (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-10-27T05:18:55', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '05362a3b-aff3-4444-bcee-4adcfbde6ef6' User entered 'No (N)' | System | 27 Oct 2020 09:19:06 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-10-27T05:19:03', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: '05362a3b-aff3-4444-bcee-4adcfbde6ef6' User entered '27 Oct 2020 05:19:03' | System | 27 Oct 2020 09:19:06 |
| | System | 27 Oct 2020 09:19:06 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '27 Oct 2020 00:01' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '31 Oct 2020 23:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 78' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[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 (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-11-03T05:54:46', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c55eccf3-30f4-4102-9a0b-3d82035e1b42' | System | 03 Nov 2020 10:55:01 |
| User entered 'No (N)' | System | 03 Nov 2020 10:55:01 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

Have you been exposed to someone with 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 (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-11-03T05:54:52', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c55eccf3-30f4-4102-9a0b-3d82035e1b42' | System | 03 Nov 2020 10:55:01 |
| User entered 'No (N)' | System | 03 Nov 2020 10:55:01 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-11-03T05:54:59', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'c55eccf3-30f4-4102-9a0b-3d82035e1b42' | System | 03 Nov 2020 10:55:01 |
| User entered '03 Nov 2020 05:54:59' | System | 03 Nov 2020 10:55:01 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '03 Nov 2020 00:01' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '07 Nov 2020 23:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered 'Day 92' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[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 (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-11-17T04:17:14', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'a6ffaca9-c05e-4796-a887-ada85de39f6e' User entered 'No (N)' | System | 17 Nov 2020 09:17:42 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

Have you been exposed to someone with 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 (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-11-17T04:17:24', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'a6ffaca9-c05e-4796-a887-ada85de39f6e' | System | 17 Nov 2020 09:17:42 |
| User entered 'No (N)' | System | 17 Nov 2020 09:17:42 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F6E8B0ED-9C80-4E7B-8DE0-DF04FA8D6F10)', Time: '2020-11-17T04:17:39', User OID: 'PatientReportedOutcome (US3022193)', ODM File OID: 'a6ffaca9-c05e-4796-a887-ada85de39f6e' User entered '17 Nov 2020 04:17:39' | System | 17 Nov 2020 09:17:42 |
| | System | 17 Nov 2020 09:17:42 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '17 Nov 2020 00:01' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| Data entry locked. | System | 20 Aug 2020 16:49:43 |
| User entered '21 Nov 2020 23:59' | System | 20 Aug 2020 16:49:43 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 61' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Oct 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '21 Oct 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 68' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Oct 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '28 Oct 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 75' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '31 Oct 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '04 Nov 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '07 Nov 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '11 Nov 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '14 Nov 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '18 Nov 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:06

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 23:42:50 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 23:42:50 |

US3022193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 10 Nov 2020 19:12:22 |

US3022193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '10 Nov 2020' | (b) (4), (b) (6) | 10 Nov 2020 19:12:22 |

US3022193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 10 Nov 2020 19:12:22 |

US3022193

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:06

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 19:12:22 |

US3022193

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 10 Nov 2020 19:12:27 |

US3022193

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:06

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 10 Nov 2020 19:12:27 |

US3022193

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:06

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Shanice Bennett (b) (4) | 09 Oct 2020 12:44:55 |
| User entered 'No (N)' | Shanice Bennett (b) (4) | 17 Sep 2020 19:33:55 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:47:39 |
| User entered 'USA-US051-2020-mRNA-1273-P301000007' | System | 09 Oct 2020 16:47:33 |
| User entered 'New' | (b) (4), (b) (6) | 09 Oct 2020 16:47:33 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Ovarian and fallopian tube disorders, HLT: Ovarian and fallopian tube cysts and neoplasms, PT: Ovarian cyst, LLT: Ovarian cyst - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:34:22 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:34:22 |
| Data point term sent to Coder | System | 09 Oct 2020 12:47:08 |
| User entered 'Ovarian Cysts (Right)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '17 Sep 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Oct 2020 12:46:40 |
| User entered '05:00' reason for change: Data Entry Error | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 09 Oct 2020 12:46:16 |
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'PV Query: Per the SAE form, the start date for the event was 06 Oct 2020; however, the EDC has a start date of 17 Sep 2020. Please confirm start date for the event of ovarian cysts (right).' (Site from Safety). | (b) (4), (b) (6) | 19 Oct 2020 16:54:17 |
| User entered '17 Sep 2020 05:00' | System | 09 Oct 2020 12:46:40 |
| User entered empty. | System | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered '07 Oct 2020' reason for change: Data Entry Error | Shanice Bennett (b) (4) | 09 Oct 2020 13:44:07 |
| User entered '06 Oct 2020' | Shanice Bennett (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Oct 2020 12:46:40 |
| User entered '11:00' reason for change: Data Entry Error | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:40 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 09 Oct 2020 12:46:16 |
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '07 Oct 2020 11:00' | System | 09 Oct 2020 13:44:07 |
| User entered '06 Oct 2020 11:00' | System | 09 Oct 2020 12:46:40 |
| User entered empty. | System | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Shanice Bennett (b) (4) | 09 Oct 2020 12:46:16 |
| | (b) (4) | |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 12:47:42 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 09 Oct 2020 12:47:42 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Shanice Bennett (b) (4) | 09 Oct 2020 12:47:42 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 12:46:16 |
| User entered empty. | Shanice Bennett (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Death](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 09 Oct 2020 12:47:59 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System). | System | 09 Oct 2020 12:47:59 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 09 Oct 2020 12:46:40 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | System | 09 Oct 2020 12:46:40 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 09 Oct 2020 12:46:40 |
| User entered '1' reason for change: Data Entry Error | Shanice Bennett (b) (4) | 09 Oct 2020 12:46:40 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 09 Oct 2020 12:46:16 |
| User entered '0' | Shanice Bennett (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '06 Oct 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '07 Oct 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | Shanice Bennett (b) (4) | 09 Oct 2020 12:47:59 |
| User entered empty. | Shanice Bennett (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'None (NONE)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[None](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered 'I' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered 'I' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Outcome](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 17 Nov 2020 02:10:30 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'There not any results to upload for this.' (Site from Safety). | Morgan Deal (b) (4) (b) (4) | 13 Nov 2020 21:01:27 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 28 Oct 2020 18:55:39 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 23 Oct 2020 20:37:10 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 23 Oct 2020 20:37:06 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No available ' (Site from Safety). | Shanice Bennett (b) (4) (b) (4) | 22 Oct 2020 15:43:50 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Test not done' (Site from Safety). | Shanice Bennett (b) (4) (b) (4) | 22 Oct 2020 15:43:40 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 19 Oct 2020 16:54:03 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 19 Oct 2020 16:53:57 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered 'Subject reported having a hysterectomy due to the ovarian cyst.' reason for change: Data Entry Error | Shanice Bennett (b) (4) | 09 Oct 2020 12:47:42 |
| User entered empty. | Shanice Bennett (b) (4) | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Oct 2020 12:47:42 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 09 Oct 2020 12:46:16 |

US3022193

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Oct 2020 12:47:59 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis atopic, LLT: Atopic dermatitis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Nov 2020 21:58:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Nov 2020 21:58:36 |
| Data point term sent to Coder | System | 09 Nov 2020 16:38:11 |
| User entered 'ATOPIC DERMATATIS' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '06 Oct 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Nov 2020 19:13:12 |
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered '13 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Nov 2020 19:13:12 |
| User entered empty. | Shanice Bennett (b) (4) | 09 Nov 2020 16:37:34 |
| | (b) (4) | |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Severity](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Death](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[None](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered 'I' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Nov 2020 19:13:12 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Shanice Bennett (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Nov 2020 16:37:34 |

US3022193

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 09 Nov 2020 16:37:34 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:15:59 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Aug 2020 17:18:17 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Aug 2020 17:18:17 |
| Data point term sent to Coder | System | 20 Aug 2020 17:17:35 |
| User entered 'levothyroxine' | Stella Yoon (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|--------------------------------|----------------------|
| User entered 'hypothyroidism' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '50' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'ug (ug)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User entered 'once daily (QD)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:51:11 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System). | Stella Yoon (b) (4) | 20 Aug 2020 17:19:05 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 20 Aug 2020 17:16:46 |
| User entered 'un UNK 1980' | Stella Yoon (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 20 Aug 2020 17:16:46 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:18:18 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 20 Aug 2020 17:18:18 |
| Data point term sent to Coder | System | 20 Aug 2020 17:17:39 |
| User entered 'alendronate' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| User entered 'osteopenia' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------|----------------------|
| User entered '70' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User entered 'every week (QS)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:51:11 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System). | Stella Yoon (b) (4) | 20 Aug 2020 17:19:00 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 20 Aug 2020 17:17:33 |
| User entered 'un UNK 2010' | Stella Yoon (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

Start date completely unknown

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '803 (803)' | System | 20 Aug 2020 17:17:33 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Aug 2020 17:19:20 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 20 Aug 2020 17:19:20 |
| Data point term sent to Coder | System | 20 Aug 2020 17:18:40 |
| User entered 'acetaminophen' | Stella Yoon (b) (4) | 20 Aug 2020 17:18:12 |
| | (b) (4) | |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------------|----------------------|
| User entered 'headache pain' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|--------------------------------|----------------------|
| User entered '325' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'mg (mg)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------|----------------------|
| User entered 'as needed (PRN)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 05:51:11 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System). | Stella Yoon (b) (4) | 20 Aug 2020 17:18:55 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 20 Aug 2020 17:18:12 |
| User entered 'un UNK 2015' | Stella Yoon (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|--------------------------------|----------------------|
| User entered '0' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|--------------------------------|----------------------|
| User entered 'Yes (Y)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|--------------------------------|----------------------|
| User entered empty. | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|--------------------------------|----------------------|
| User entered 'No (N)' | Stella Yoon (b) (4) (b) (4) | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Aug 2020 17:18:12 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:35:22 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:35:22 |
| Data point term sent to Coder | System | 09 Oct 2020 12:51:12 |
| User entered 'oxycodone' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| User entered 'Ovarian cysts' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------------------------|----------------------|
| User entered '325' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'mg (mg)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User entered 'as needed (PRN)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '06 Oct 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User closed query 'Per CDM: Please answer with Yes or No to the "Ongoing" question as this field is not to remain empty. Thank you ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 12:40:13 |
| Query 'Per CDM: Please answer with Yes or No to the "Ongoing" question as this field is not to remain empty. Thank you ' answered with 'updated' (Site from DM). | Shanice Bennett (b) (4) | 20 Nov 2020 16:39:15 |
| User entered 'No (N)' reason for change: Per Query Resolution | Shanice Bennett (b) (4) | 20 Nov 2020 16:39:01 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 17 Nov 2020 08:19:54 |
| User opened query 'Per CDM: Please answer with Yes or No to the "Ongoing" question as this field is not to remain empty. Thank you ' (Site from DM). | (b) (4), (b) (6) | 17 Nov 2020 08:19:52 |
| User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 17 Nov 2020 08:18:54 |
| Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System). | Morgan Deal (b) (4) | 14 Nov 2020 00:18:08 |
| Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). | Morgan Deal (b) (4) | 14 Nov 2020 00:18:03 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Nov 2020 00:17:48 |
| User entered empty; reason for change Per Query Resolution | Morgan Deal (b) (4) | 14 Nov 2020 00:17:48 |
| User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 21:10:09 |
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered '10 Oct 2020' reason for change: Per Query Resolution | Morgan Deal (b) (4) | 14 Nov 2020 00:17:48 |
| User entered empty. | (b) (4) | |
| | Shanice Bennett (b) (4) | 09 Oct 2020 12:50:53 |
| | (b) (4) | |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 12:50:53 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:29:22 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:29:22 |
| Data point term sent to Coder | System | 09 Oct 2020 12:53:16 |
| User entered 'Ibuprofen' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| User entered 'Ovarian cysts' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------------------------|----------------------|
| User entered '800' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'mg (mg)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| User entered 'as needed (PRN)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '06 Oct 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

Start date completely unknown

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User closed query 'Per CDM: Please answer with Yes or No to the "Ongoing" question as this field is not to remain empty. Thank you ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 12:40:23 |
| Query 'Per CDM: Please answer with Yes or No to the "Ongoing" question as this field is not to remain empty. Thank you ' answered with 'updated' (Site from DM). | Shanice Bennett (b) (4) | 20 Nov 2020 16:39:36 |
| User entered 'No (N)' reason for change: Per Query Resolution | Shanice Bennett (b) (4) | 20 Nov 2020 16:39:28 |
| User opened query 'Per CDM: Please answer with Yes or No to the "Ongoing" question as this field is not to remain empty. Thank you ' (Site from DM). | (b) (4), (b) (6) | 17 Nov 2020 08:20:31 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 17 Nov 2020 08:20:28 |
| User closed query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 17 Nov 2020 08:20:26 |
| Query 'Data is required. Please complete.' answered with 'UPDATED' (Site from System). | Morgan Deal (b) (4) | 14 Nov 2020 00:18:42 |
| Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). | Morgan Deal (b) (4) | 14 Nov 2020 00:18:37 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Nov 2020 00:18:30 |
| User entered empty; reason for change Per Query Resolution | Morgan Deal (b) (4) | 14 Nov 2020 00:18:30 |
| User opened query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 21:10:37 |
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered '08 Oct 2020' reason for change: Per Query Resolution | Morgan Deal (b) (4) | 14 Nov 2020 00:18:30 |
| User entered empty. | (b) (4) | |
| | Shanice Bennett (b) (4) | 09 Oct 2020 12:52:37 |
| | (b) (4) | |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Oct 2020 12:52:37 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:27:18 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 13:27:18 |
| Data point term sent to Coder | System | 09 Oct 2020 12:54:16 |
| User entered 'Docusate sodium' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------------------|----------------------|
| User entered 'ovarian cysts' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------------------------|----------------------|
| User entered '100' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------------------------|----------------------|
| User entered 'mg (mg)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------------------|----------------------|
| User entered 'twice daily (BID)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '06 Oct 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------------------------|----------------------|
| User entered '0' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Oct 2020 20:03:38 |
| User entered 'Yes (Y)' | Shanice Bennett (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered '10 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Oct 2020 20:03:38 |
| User entered empty. | Shanice Bennett (b) (4) | 09 Oct 2020 12:53:30 |
| | (b) (4) | |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------------------------|----------------------|
| User entered 'No (N)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 08:43:06

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Oct 2020 12:53:30 |

US3022193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:06

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Shanice Bennett (b) (4) | 09 Oct 2020 12:44:24 |
| User entered 'No (N)' | Shanice Bennett (b) (4) | 17 Sep 2020 19:34:00 |

US3022193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:06

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| User entered '06 Oct 2020' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:44:45 |

US3022193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:06

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------------------------|----------------------|
| User entered 'Hysterectomy' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:44:45 |

US3022193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:06

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------------------------|----------------------|
| User entered 'Adverse Event (AE)' | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:44:45 |

US3022193

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:06

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------------------------|----------------------|
| User entered empty. | Shanice Bennett (b) (4) (b) (4) | 09 Oct 2020 12:44:45 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:47:58 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:47:55 |
| User entered 'USA-US051-2020-MRNA-1273-P301000007' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Yes (Y)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Yes (Y)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Paul' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Bradley' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered '340 Eisenhower Dr.' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Savannah' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: State](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'GA' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered '31406' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 20:37:25 |
| User entered 'US' | System | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 23 Oct 2020 20:37:35 |
| User entered '1' | System | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:47:58 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:47:55 |
| User entered 'USA-US051-2020-MRNA-1273-P301000007' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Yes (Y)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Yes (Y)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Paul' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Bradley' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered '340 Eisenhower Dr.' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Savannah' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: State](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'GA' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered '31406' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 20:37:25 |
| User entered 'US' | System | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 23 Oct 2020 20:37:35 |
| User entered '1' | System | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:06

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '09/Oct/2020 16:48' | System | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 20:37:25 |
| User entered 'I' | (b) (4), (b) (6) | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| Un-reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:47:58 |
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:47:55 |
| User entered 'USA-US051-2020-MRNA-1273-P301000007' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Yes (Y)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Life threatening](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Yes (Y)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'No (N)' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Paul' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Bradley' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-----------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered '340 Eisenhower Dr.' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: City](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'Savannah' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: State](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered 'GA' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 09 Oct 2020 16:48:02 |
| User entered '31406' | System | 09 Oct 2020 16:47:33 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[Investigator Country](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 23 Oct 2020 20:37:25 |
| User entered 'US' | System | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 23 Oct 2020 20:37:35 |
| User entered '1' | System | 09 Oct 2020 16:48:08 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:06

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23/Oct/2020 20:37' | System | 23 Oct 2020 20:37:35 |

US3022193

Folder: SAE USA-US051-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 23 Oct 2020 20:37:35 |