

US3362285 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:00:45

All time stamps listed in this document are displayed in GMT

US3362285

Form: Participant Creation

Generated On: 26 Nov 2020 11:00:45

[Participant ID](#)

US3362285

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 24 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 | SCRN |

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1954 |
| Age | 66 |
| Age Units | YEARS |
| Age (Derived) | 66 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | False |
| Black | True |
| 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 11:00:45

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 24 SEP 2020 |
| Month and Year of Informed Consent (derived) | SEP 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input type="radio"/> |
| | Amendment 3 <input checked="" type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:00:45

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:00:45

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Condition | BENIGN PROSTATE HYPERTROPHY |
| Start date (dd MMM yyyy) | UN UNK 2013 |
| 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 2013 |
| Start Year (derived) | 2013 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Condition | DRUG ALLERGY - PENICILLIN |
| Start date (dd MMM yyyy) | UN UNK 1955 |
| 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 1955 |
| Start Year (derived) | 1955 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Condition | DRUG ALLERGY - CLARITHROMYCIN |
| Start date (dd MMM yyyy) | UN UNK 2015 |
| 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 2015 |
| Start Year (derived) | 2015 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 24 SEP 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 10:22 (24 HR) |
| Vital Signs Date and Time (derived) | 24 SEP 2020 10:22 |
| Height (<i>xxx.x</i>) | 183 cm |
| Weight (<i>xxx.x</i>) | 118.6 kg |
| BMI (<i>xxx.x</i>) | 35.41461 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 11:00:45

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 24 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 | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

What was the date of randomization? (dd MMM yyyy) 24 SEP 2020

What was the participant's randomization number? 189374

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 11:00:45

| | |
|--------|---------------|
| 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 11:00:45

| | |
|-------------------------------------|--|
| 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) | 24 SEP 2020 |
| Time of assessment (00:00-23:59) | 08:36 (24 HR) |
| Vital Signs Date and Time (derived) | 24 SEP 2020 08:36 |
| 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) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 144 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 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 11:00:45

| | |
|-------------------------------------|--|
| 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) | 24 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:22 (24 HR) |
| Vital Signs Date and Time (derived) | 24 SEP 2020 10:22 |
| 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) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 112 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

| | |
|--|--|
| 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) | 24 SEP 2020 |
| What was the treatment time? (00:00-23:59) | 09:46 (24 HR) |
| Treatment Date and Time (derived) | 24 SEP 2020 09:46 |
| 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 |

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 24 SEP 2020 |
| Collection time (<i>00:00-23:59</i>) | 09:02 (24 HR) |
| Collection date and time (derived) | 24 SEP 2020 09:02 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:45

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 24 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 | 09:08 | 24 SEP 2020 09:08 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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 11:00:45

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

98.1 °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

24 SEP 2020 10:21

PC Open Date & Time

24 SEP 2020 10:06

PC Close Date & Time

24 SEP 2020 12:36

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 24 SEP 2020 20:26 |
| PC Open Date & Time | 24 SEP 2020 13:31 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

25 SEP 2020 12:42

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

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

26 SEP 2020 14:07

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 13:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

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

97.1 °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

28 SEP 2020 21:21

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 12:54

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

30 SEP 2020 14:24

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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

24 SEP 2020 10:22

PC Open Date & Time

24 SEP 2020 10:06

PC Close Date & Time

24 SEP 2020 12:36

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

24 SEP 2020 20:27

PC Open Date & Time

24 SEP 2020 13:31

PC Close Date & Time

25 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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

25 SEP 2020 12:43

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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

26 SEP 2020 14:08

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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

27 SEP 2020 13:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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

28 SEP 2020 21:21

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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

29 SEP 2020 12:55

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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

30 SEP 2020 14:24

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 24 SEP 2020 10:24 |
| PC Open Date & Time | 24 SEP 2020 10:06 |
| PC Close Date & Time | 24 SEP 2020 12:36 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 24 SEP 2020 20:28 |
| PC Open Date & Time | 24 SEP 2020 13:31 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 SEP 2020 12:43 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 SEP 2020 14:09 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 SEP 2020 13:36 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 SEP 2020 21:22 |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 SEP 2020 12:55 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 SEP 2020 14:25 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

Was Contact Attempted?

Yes ☒

No ☐

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

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362285

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 22 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 | VISIT2 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

| | |
|-------------------------------------|---|
| 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) | 22 OCT 2020 |
| Time of assessment (00:00-23:59) | 08:00 (24 HR) |
| Vital Signs Date and Time (derived) | 22 OCT 2020 08:00 |
| 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) | 82 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 136 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 88 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

| | |
|-------------------------------------|--|
| 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) | 22 OCT 2020 |
| Time of assessment (00:00-23:59) | 10:22 (24 HR) |
| Vital Signs Date and Time (derived) | 22 OCT 2020 10:22 |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 140 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 76 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

| | |
|--|--|
| 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) | 22 OCT 2020 |
| What was the treatment time? (00:00-23:59) | 08:42 (24 HR) |
| Treatment Date and Time (derived) | 22 OCT 2020 08:42 |
| 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 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 22 OCT 2020 |
| Collection time (<i>00:00-23:59</i>) | 08:11 (24 HR) |
| Collection date and time (derived) | 22 OCT 2020 08:11 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:45

| | | | |
|--|---------------------------|--|------------------------------------|
| Collection date (<i>dd MMM yyyy</i>) | | | 22 OCT 2020 |
| Lab Test | Was the sample collected? | Collection time (<i>00:00 - 23:59</i>) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 08:10 | 22 OCT 2020 08:10 |
| Nasopharyngeal Swab 2 | No | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

22 OCT 2020 09:16

PC Open Date & Time

22 OCT 2020 09:02

PC Close Date & Time

22 OCT 2020 11:32

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 97.3 °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 | 22 OCT 2020 13:58 |
| PC Open Date & Time | 22 OCT 2020 12:27 |
| PC Close Date & Time | 23 OCT 2020 11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp 23 OCT 2020 12:30

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 12:16

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

25 OCT 2020 13:39

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

26 OCT 2020 14:45

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 12:55

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

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

97.3 °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

28 OCT 2020 17:46

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

22 OCT 2020 09:02

PC Close Date & Time

22 OCT 2020 11:32

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

22 OCT 2020 13:59

PC Open Date & Time

22 OCT 2020 12:27

PC Close Date & Time

23 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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

23 OCT 2020 12:31

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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

24 OCT 2020 12:17

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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

25 OCT 2020 13:40

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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

26 OCT 2020 14:45

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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

27 OCT 2020 12:57

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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

28 OCT 2020 17:47

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

22 OCT 2020 09:02

PC Close Date & Time

22 OCT 2020 11:32

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 22 OCT 2020 14:00 |
| PC Open Date & Time | 22 OCT 2020 12:27 |
| PC Close Date & Time | 23 OCT 2020 11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 OCT 2020 12:33 |
| PC Open Date & Time | 23 OCT 2020 12:00 |
| PC Close Date & Time | 24 OCT 2020 11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 OCT 2020 12:18 |
| PC Open Date & Time | 24 OCT 2020 12:00 |
| PC Close Date & Time | 25 OCT 2020 11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 25 OCT 2020 13:40 |
| PC Open Date & Time | 25 OCT 2020 12:00 |
| PC Close Date & Time | 26 OCT 2020 11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 OCT 2020 14:46 |
| PC Open Date & Time | 26 OCT 2020 12:00 |
| PC Close Date & Time | 27 OCT 2020 11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 OCT 2020 12:59 |
| PC Open Date & Time | 27 OCT 2020 12:00 |
| PC Close Date & Time | 28 OCT 2020 11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 ☒

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 28 OCT 2020 17:48 |
| PC Open Date & Time | 28 OCT 2020 12:00 |
| PC Close Date & Time | 29 OCT 2020 11:59 |

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

Was Contact Attempted?

Yes ☒

No ☐

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

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362285

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

Was Contact Attempted?

Yes ☒

No ☐

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

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362285

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

Was Contact Attempted?

Yes ☒

No ☐

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

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3362285

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 16 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 16 NOV 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 07:42 (24 HR) |
| Vital Signs Date and Time (derived) | 16 NOV 2020 07:42 |
| Temperature (<i>xxx.x</i>) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 89 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 139 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 16 NOV 2020 |
| Collection time (<i>00:00-23:59</i>) | 07:55 (24 HR) |
| Collection date and time (derived) | 16 NOV 2020 07:55 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 25 NOV 2020 23:59 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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 <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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 13 JAN 2021 23:59 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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 <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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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 <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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 187 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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 <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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 28 APR 2021 23:59 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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 <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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 07 JUL 2021 23:59 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 313 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 369 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 376 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 06 OCT 2021 23:59 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 397 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 432 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 523 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

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09 MAR 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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 <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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I 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 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 06 APR 2022 23:59 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 579 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 593 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 628 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 15 JUN 2022 23:59 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 656 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 663 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 754 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 761 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| 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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 775 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 789 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

| TIMEPOINT | DAY 796 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

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

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

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Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

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Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:00:45

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:00:45

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

| | |
|--|--|
| AEID | USA-US112-2020-MRNA-1273-P30 1000011 |
| Adverse event | CEREBROVASCULAR ACCIDENT |
| 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) | 16 NOV 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 18 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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 | True |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 16 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 18 NOV 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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

PATIENT CONTACTED SITE
-SENT TO ER ON NIGHT OF
16NOV2020 FOR DIFFICULTY
SPEAKING AND DIAGNOSED
WITH CEREBROVASCULAR
ACCIDENT. ADMITTED TO
HOSPITAL 16NOV-18NOV2020;
STATED ONLY NEW
MEDICATION WAS FULL DOSE
ASPRIN 325MG RIGHT NOW;
WILL COME TO SIGN MEDICAL
RELEASE AND UPDATE
ACCORDINGLY, HAS FOLLOW
UP WITH CARDIOLOGIST
REPORTS CAUSE OF CVA LEFT
CORONARY ARTERY
OCCLUSION - WILL CONFIRM
WITH MEDICAL RECORDS.

| | |
|--|---|
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | 0 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:00:45

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

Yes ☒

No ☐

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

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------------|--|
| Name of Medication | LOSARTAN/HYDROCHLOROTHIAZIDE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | HYPERTENSION |
| Dose per administration | 100/25 |
| 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 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"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2001 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------------|--|
| Name of Medication | ZETIA |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | HYPERLIPIDEMIA |
| Dose per administration | 10 |
| 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 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------|--|
| Name of Medication | GLIPIZIDE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | DIABETES TYPE II |
| Dose per administration | 4 |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

| | |
|--|--------------------------------------|
| Respiratory (Inhalation) | <input type="checkbox"/> |
| Intralesional | <input type="checkbox"/> |
| Intraperitoneal | <input type="checkbox"/> |
| Nasal | <input type="checkbox"/> |
| Vaginal | <input type="checkbox"/> |
| Rectal | <input type="checkbox"/> |
| Intravenous | <input type="checkbox"/> |
| Intravenous Bolus | <input type="checkbox"/> |
| Intravenous Drip | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| Start date completely unknown | False |
| Ongoing? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | |
| Was this medication taken for solicited event? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 |
| Interval Dosage Unit Number (derived) | 1 |
| Interval Dosage Definition (derived) | 802 <input type="radio"/> |
| | 803 <input type="radio"/> |
| | 804 <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------|--|
| Name of Medication | TRULICITY |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | DIABETES TYPE II |
| Dose per administration | 1.5 |
| 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 checked="" 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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input checked="" 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 (4)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------|--|
| Name of Medication | JARDIANCE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | DIABETES TYPE II |
| Dose per administration | 25 |
| 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 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------------|---|
| Name of Medication | TAMSULOSIN |
| Prophylaxis | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> |
| Indication | BENIGN PROSTATE HYPERTROPHY |
| Dose per administration | 0.4 |
| 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 checked="" 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 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2013 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------|--|
| Name of Medication | FINASTERIDE |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | BENIGN PROSTATE HYPERTROPHY |
| Dose per administration | 5 |
| 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 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| <hr/> | | |
| If route of administration is Other, specify <hr/> | | |
| Start date (dd MMM yyyy) | UN UNK 2013 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| <hr/> | | |
| If not Ongoing, End date (dd MMM yyyy) <hr/> | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| <hr/> | | |
| 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"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------|--|
| Name of Medication | MOBIC |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | ANXIETY |
| Dose per administration | 15 |
| 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 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"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

| | | |
|---|--------------------------|----------------------------------|
| | 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 2018 |
| 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) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------|--|
| Name of Medication | ASPIRIN |
| Prophylaxis | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Indication | CARDIAC HEALTH |
| Dose per administration | 81 |
| 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 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"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------------|--|
| Name of Medication | INFLUENZA VACCINE |
| Prophylaxis | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Indication | INFLUENZA PREVENTION |
| Dose per administration | 0.5 |
| Dose unit | mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" 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 type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

| | | |
|---|--------------------------|-------------------------------------|
| | 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) | | 11 NOV 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) | | 11 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| <hr/> | | |
| Separate Dosage Number (derived) | | <input type="text"/> |
| Interval Dosage Unit Number (derived) | | <input type="text"/> |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------------|--|
| Name of Medication | PNEUMONIA VACCINE |
| Prophylaxis | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Indication | PNEUMONIA PREVENTION |
| Dose per administration | 0.5 |
| Dose unit | mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" 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 type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/> |
| If frequency is Other, specify _____ | |
| Route of administration | Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 11 NOV 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 11 NOV 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

| | |
|--------------------------------------|--|
| Name of Medication | CLOPIDOGREL |
| Prophylaxis | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Indication | PREVENTION OF CEREBROVASCULAR ACCIDENT |
| Dose per administration | 75 |
| 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 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"/> |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 24 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3362285

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:00:45

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3362285

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:00:45

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

US3362285

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:00:45

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 ☐

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

| | |
|--|---|
| SAEID | USA-US112-2020-MRNA-1273-P301000011 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 1 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:45

| | |
|---|--|
| SAEID | USA-US112-2020-MRNA-1273-P301000011 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input checked="" type="radio"/> No <input 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 | JORDAN |
| Investigator's Last Name | WHATLEY |
| Site Address: Street | 5326 O'DONOVAN DR |
| Site Address: City | BATON ROUGE |
| Site Address: State | |
| Site Address: Postal Code | 70808 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 1 |
| Date of submission (Pre-filled from custom function) | 24/NOV/2020 00:23 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3362285 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

US3362285

Form: Participant Creation

Generated On: 26 Nov 2020 11:00:45

[Participant ID](#)

| Audit | User | Time (GMT) |
|--------------------------|---|----------------------|
| User entered 'US3362285' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 24 Sep 2020 13:19:26 |

US3362285

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential (if applicable) and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 19:20:29 |
| Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential (if applicable) and Risk of Exposure eCRF forms. Please update as needed. ' answered with 'data updated per query resolution' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 15:27:17 |
| User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential (if applicable) and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 21:19:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 15:00:48 |

US3362285

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| User entered '24 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 24 Sep 2020 13:19:27 |

US3362285

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 24 Sep 2020 15:00:48 |
| | | |

US3362285

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'SCRN' | System | 24 Sep 2020 15:00:48 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User closed query 'Per CDM: Demographics data is required, please update the eCRF form as needed. ' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 19:20:08 |
| Query 'Per CDM: Demographics data is required, please update the eCRF form as needed. ' answered with 'Data updated per query resolution. ' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 14:35:18 |
| User opened query 'Per CDM: Demographics data is required, please update the eCRF form as needed. ' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 21:19:27 |
| User entered (b) (6) 1954' | RWS_ENDPOINT ENDPOINT (b) (4) | 24 Sep 2020 13:19:29 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Age](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '66' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| User entered 'YEARS' | System | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered '66' | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Sex](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| User entered 'Male (M)' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

White

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Black](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Asian](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Other](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

Unknown

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:00:45

[Not reported](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 14:33:45 |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 15:02:02 |
| | | |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Sep 2020' | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2020' | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | System | 24 Sep 2020 15:02:17 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 24 Sep 2020 15:02:17 |
| User entered 'Amendment 3 (3)' reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Sep 2020 15:02:17 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 24 Sep 2020 15:02:02 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 15:02:02 |
| | | |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 15:02:02 |
| | | |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 15:02:02 |
| | | |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 24 Sep 2020 15:02:02 |
| | | |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------|--|----------------------|
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED] | 24 Sep 2020 13:19:27 |

US3362285

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:00:45

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 15:00:53 |
| | | |

US3362285

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:00:45

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:07:03 |
| | | |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:09:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:09:47 |
| Data point term sent to Coder | System | 30 Sep 2020 15:08:29 |
| User entered 'HYPERTENSION' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2001' | (b) (4), (b) (6) | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2001' | System | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2001' | System | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:07:34 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:09:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:09:47 |
| Data point term sent to Coder | System | 30 Sep 2020 15:08:30 |
| User entered 'HYPERLIPIDEMIA' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:07:48 |
| | | |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:07:48 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:09:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:09:48 |
| Data point term sent to Coder | System | 30 Sep 2020 15:08:30 |
| User entered 'DIABETES TYPE II' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2001' | (b) (4), (b) (6) | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2001' | System | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2001' | System | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:08:06 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hypertrophy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:17:53 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:17:53 |
| Data point term sent to Coder | System | 30 Sep 2020 15:08:31 |
| User entered 'BENIGN PROSTASTE HYPERTROPHY' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:08:28 |
| | | |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2013' | System | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2013' | System | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:08:28 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' canceled (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 17:01:20 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 14:05:31 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intervertebral disc operation, LLT: Lumbar discectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:10:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:10:50 |
| Data point term sent to Coder | System | 30 Sep 2020 15:09:31 |
| User entered 'LUMBAR DISCETOMY' | (b) (4), (b) (6) | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2018' | System | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2018' | System | 30 Sep 2020 15:08:47 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Vascular therapeutic procedures NEC, PT: Vascular stent insertion, LLT: Vascular stent insertion - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Oct 2020 12:07:33 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Oct 2020 12:07:33 |
| Data point term sent to Coder | System | 30 Sep 2020 15:09:34 |
| User entered 'RIGHT VASCULAR STENT PLACEMENT' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2019' | (b) (4), (b) (6) | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2019' | (b) (4), (b) (6) | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2019' | System | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2019' | System | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2019' | System | 30 Sep 2020 15:09:09 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:10:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:10:50 |
| Data point term sent to Coder | System | 30 Sep 2020 15:09:34 |
| User entered 'DRUG ALLERGY - PENICILLIN' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 1955' | (b) (4), (b) (6) | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:09:29 |
| | | |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 1955' | System | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1955' | System | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:09:29 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:19:55 |
| User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:19:55 |
| Data point term sent to Coder | System | 30 Sep 2020 15:10:37 |
| User entered 'DRUG ALLERGY - CLARITHROMYCIN' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2015' | (b) (4), (b) (6) | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:10:00 |
| | | |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2015' | System | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2015' | System | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:10:00 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:13:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:13:54 |
| Data point term sent to Coder | System | 30 Sep 2020 15:12:42 |
| User entered 'DRUG ALLERGY - STATINS' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2014' | (b) (4), (b) (6) | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:11:44 |
| | | |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------|--------|----------------------|
| User entered 'Jan 2014' | System | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '2014' | System | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:11:44 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '10:22' | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:22' | System | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered '183' cm | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |
| DataPoint set to visible. | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Weight (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User closed query 'Per CDM: Please confirm weight and update if necessary. Thank you.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 20:24:36 |
| Query 'Per CDM: Please confirm weight and update if necessary. Thank you.' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 18:34:45 |
| User entered '118.6' kg reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Oct 2020 18:34:31 |
| User opened query 'Per CDM: Please confirm weight and update if necessary. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 15:02:21 |
| User entered '35.4' kg | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |
| DataPoint set to visible. | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered '35.41461' | System | 07 Oct 2020 18:34:31 |
| User entered '10.57064' | System | 30 Sep 2020 15:13:35 |
| DataPoint set to visible. | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|--------|----------------------|
| User entered 'kg/m2' | System | 30 Sep 2020 15:13:35 |
| DataPoint set to visible. | System | 24 Sep 2020 15:02:02 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered missing code ND - Not Done. | (b) (4), (b) (6) | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 30 Sep 2020 15:13:35 |

US3362285

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:13:56 |

US3362285

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:13:56 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |
| | | |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

[Other](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |
| | | |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

No Risk Identified

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered 'I' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

[Other](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:00:45

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:14:43 |

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 15:01:04 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 15:01:04 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 24 Sep 2020 15:01:04 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT1' | System | 24 Sep 2020 15:01:04 |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| User entered '24 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 24 Sep 2020 14:24:36 |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|-----------------------|---|----------------------|
| User entered '189374' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 24 Sep 2020 14:24:36 |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| User entered '>=65 years (3)' | RWS_ENDPOINT ENDPOINT (b) (4) <div></div> | 24 Sep 2020 14:24:36 |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

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)' | (b) (4), (b) (6) | 24 Sep 2020 15:01:40 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 24 Sep 2020 15:01:40 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 24 Sep 2020 15:01:40 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 15:01:40 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

[Liver Disease](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 24 Sep 2020 15:01:40 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:14:58 |
| DataPoint set to visible. | System | 24 Sep 2020 15:02:17 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:45

Height

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:27 |
| User entered '183' cm reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Sep 2020 17:05:33 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:45

[Weight](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:47 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:27 |
| User entered '118.6' kg reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Sep 2020 17:05:33 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:45

Height

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:27 |
| User entered '183' cm reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Sep 2020 17:05:33 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:45

[Weight](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:47 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:27 |
| User entered '118.6' kg reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Sep 2020 17:05:33 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '08:36' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 08:36' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered '36.7' C | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '72' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '18' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '144' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '73' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:45

Height

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:27 |
| User entered '183' cm reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Sep 2020 17:05:33 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:00:45

[Weight](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:47 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:48:27 |
| User entered '118.6' kg reason for change: Data Entry Error | (b) (4), (b) (6) | 24 Sep 2020 17:05:33 |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '10:22' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:22' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered '36.7' C | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '67' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '18' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '112' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '70' | (b) (4), (b) (6) | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 24 Sep 2020 16:42:39 |

US3362285

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System). | System | 02 Oct 2020 19:49:32 |
| User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System). | System | 02 Oct 2020 19:49:22 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:49:22 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 16:42:44 |

US3362285

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 02 Oct 2020 19:49:32 |
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 16:42:44 |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 15:02:57 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 15:02:57 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 15:02:57 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 15:02:57 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:46' | (b) (4), (b) (6) | 24 Sep 2020 15:02:57 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 09:46' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------------------|------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 24 Sep 2020 15:02:57 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:15:47 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 15:15:47 |

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:02' | (b) (4), (b) (6) | 30 Sep 2020 15:15:47 |

US3362285

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 09:02' | System | 30 Sep 2020 15:15:47 |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:45

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 15:16:06 |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:06 |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:06 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '09:08' | (b) (4), (b) (6) | 30 Sep 2020 15:16:06 |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 09:08' | System | 30 Sep 2020 15:16:06 |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:06 |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:06 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:16:06 |

US3362285

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Sep 2020 15:16:06 |

US3362285

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:11 |
| | | |

US3362285

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Sep 2020 15:16:11 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:20:16', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5' | System | 24 Sep 2020 15:21:41 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 15:21:41 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:20:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5' | System | 24 Sep 2020 15:21:41 |
| User entered '98.1' | System | 24 Sep 2020 15:21:41 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:21:29', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5' | System | 24 Sep 2020 15:21:41 |
| User entered 'No (N)' | System | 24 Sep 2020 15:21:41 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:21:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'f3fd9a7c-5f39-4ccb-9ebf-db650e3f2df5' | System | 24 Sep 2020 15:21:41 |
| User entered '24 Sep 2020 10:21' | System | 24 Sep 2020 15:21:41 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:06' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:36' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae' | System | 25 Sep 2020 01:26:56 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 01:26:56 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae' | System | 25 Sep 2020 01:26:56 |
| User entered '98.0' | System | 25 Sep 2020 01:26:56 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae' | System | 25 Sep 2020 01:26:56 |
| User entered 'No (N)' | System | 25 Sep 2020 01:26:56 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:26:54', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ccbeea26-b3c5-4fbf-80d3-ec5ffc8587ae' | System | 25 Sep 2020 01:26:56 |
| User entered '24 Sep 2020 20:26' | System | 25 Sep 2020 01:26:56 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 13:31' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 2' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:02', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6' | System | 25 Sep 2020 17:42:31 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 17:42:31 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:11', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6' | System | 25 Sep 2020 17:42:31 |
| User entered '98.2' | System | 25 Sep 2020 17:42:31 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6' | System | 25 Sep 2020 17:42:31 |
| User entered 'No (N)' | System | 25 Sep 2020 17:42:31 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e6459d9e-dc77-4c14-82cd-3b5e3248edc6' | System | 25 Sep 2020 17:42:31 |
| User entered '25 Sep 2020 12:42' | System | 25 Sep 2020 17:42:31 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 3' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2' | System | 26 Sep 2020 19:07:45 |
| User entered 'Yes (Y)' | System | 26 Sep 2020 19:07:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2' | System | 26 Sep 2020 19:07:45 |
| User entered '97.5' | System | 26 Sep 2020 19:07:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2' | System | 26 Sep 2020 19:07:45 |
| User entered 'No (N)' | System | 26 Sep 2020 19:07:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '66e6832b-5f51-49c6-a9e8-cb3fc86b8de2' | System | 26 Sep 2020 19:07:45 |
| User entered '26 Sep 2020 14:07' | System | 26 Sep 2020 19:07:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 4' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:34:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09' | System | 27 Sep 2020 18:35:14 |
| User entered 'Yes (Y)' | System | 27 Sep 2020 18:35:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09' | System | 27 Sep 2020 18:35:14 |
| User entered '97.5' | System | 27 Sep 2020 18:35:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09' | System | 27 Sep 2020 18:35:14 |
| User entered 'No (N)' | System | 27 Sep 2020 18:35:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '71017576-5945-4190-af5e-86735f844e09' | System | 27 Sep 2020 18:35:14 |
| User entered '27 Sep 2020 13:35' | System | 27 Sep 2020 18:35:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 5' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:20:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3' | System | 29 Sep 2020 02:21:14 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 02:21:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:20:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3' | System | 29 Sep 2020 02:21:14 |
| User entered '97.1' | System | 29 Sep 2020 02:21:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3' | System | 29 Sep 2020 02:21:14 |
| User entered 'No (N)' | System | 29 Sep 2020 02:21:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9546dae-3fb7-46ee-9943-00bfcd1cffe3' | System | 29 Sep 2020 02:21:14 |
| User entered '28 Sep 2020 21:21' | System | 29 Sep 2020 02:21:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 6' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7' | System | 29 Sep 2020 17:54:49 |
| User entered 'Yes (Y)' | System | 29 Sep 2020 17:54:49 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7' | System | 29 Sep 2020 17:54:49 |
| User entered '98.1' | System | 29 Sep 2020 17:54:49 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:40', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7' | System | 29 Sep 2020 17:54:49 |
| User entered 'No (N)' | System | 29 Sep 2020 17:54:49 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:45', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5931e99e-5243-4b02-a572-b6b6316c7dc7' | System | 29 Sep 2020 17:54:49 |
| User entered '29 Sep 2020 12:54' | System | 29 Sep 2020 17:54:49 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 7' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:05', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a' | System | 30 Sep 2020 19:24:28 |
| User entered 'Yes (Y)' | System | 30 Sep 2020 19:24:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a' | System | 30 Sep 2020 19:24:28 |
| User entered '96.1' | System | 30 Sep 2020 19:24:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a' | System | 30 Sep 2020 19:24:28 |
| User entered 'No (N)' | System | 30 Sep 2020 19:24:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3b292784-151e-4648-bf9d-026af317a66a' | System | 30 Sep 2020 19:24:28 |
| User entered '30 Sep 2020 14:24' | System | 30 Sep 2020 19:24:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-24T10:21:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68' | System | 24 Sep 2020 15:22:28 |
| User entered 'None (1)' | System | 24 Sep 2020 15:22:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68' | System | 24 Sep 2020 15:22:28 |
| User entered 'No (N)' | System | 24 Sep 2020 15:22:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68' | System | 24 Sep 2020 15:22:28 |
| User entered 'No (N)' | System | 24 Sep 2020 15:22:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-24T10:22:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68' | System | 24 Sep 2020 15:22:28 |
| User entered 'None (1)' | System | 24 Sep 2020 15:22:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ac5858bf-a8d3-453b-868e-678fbf766d68' | System | 24 Sep 2020 15:22:28 |
| User entered '24 Sep 2020 10:22' | System | 24 Sep 2020 15:22:28 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:06' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:36' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-24T20:27:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077' | System | 25 Sep 2020 01:27:37 |
| User entered 'None (1)' | System | 25 Sep 2020 01:27:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077' | System | 25 Sep 2020 01:27:37 |
| User entered 'No (N)' | System | 25 Sep 2020 01:27:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077' | System | 25 Sep 2020 01:27:37 |
| User entered 'No (N)' | System | 25 Sep 2020 01:27:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-24T20:27:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077' | System | 25 Sep 2020 01:27:37 |
| User entered 'None (1)' | System | 25 Sep 2020 01:27:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '8064b35a-a5d8-4181-a16a-df440f3ba077' | System | 25 Sep 2020 01:27:37 |
| User entered '24 Sep 2020 20:27' | System | 25 Sep 2020 01:27:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 13:31' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 2' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-25T12:42:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c' | System | 25 Sep 2020 17:43:03 |
| User entered 'None (1)' | System | 25 Sep 2020 17:43:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c' | System | 25 Sep 2020 17:43:03 |
| User entered 'No (N)' | System | 25 Sep 2020 17:43:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:42:45', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c' | System | 25 Sep 2020 17:43:03 |
| User entered 'No (N)' | System | 25 Sep 2020 17:43:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-25T12:42:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c' | System | 25 Sep 2020 17:43:03 |
| User entered 'None (1)' | System | 25 Sep 2020 17:43:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f23cf31-25de-4145-83dd-a546ab46873c' | System | 25 Sep 2020 17:43:03 |
| User entered '25 Sep 2020 12:43' | System | 25 Sep 2020 17:43:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 3' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-26T14:07:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a' | System | 26 Sep 2020 19:08:14 |
| User entered 'None (1)' | System | 26 Sep 2020 19:08:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:52', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a' | System | 26 Sep 2020 19:08:14 |
| User entered 'No (N)' | System | 26 Sep 2020 19:08:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:07:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a' | System | 26 Sep 2020 19:08:14 |
| User entered 'No (N)' | System | 26 Sep 2020 19:08:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-26T14:08:03', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a' | System | 26 Sep 2020 19:08:14 |
| User entered 'None (1)' | System | 26 Sep 2020 19:08:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e5781c81-874b-41f0-9d33-8bd154c6359a' | System | 26 Sep 2020 19:08:14 |
| User entered '26 Sep 2020 14:08' | System | 26 Sep 2020 19:08:14 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 4' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-27T13:35:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6' | System | 27 Sep 2020 18:35:54 |
| User entered 'None (1)' | System | 27 Sep 2020 18:35:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6' | System | 27 Sep 2020 18:35:54 |
| User entered 'No (N)' | System | 27 Sep 2020 18:35:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6' | System | 27 Sep 2020 18:35:54 |
| User entered 'No (N)' | System | 27 Sep 2020 18:35:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-27T13:35:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6' | System | 27 Sep 2020 18:35:54 |
| User entered 'None (1)' | System | 27 Sep 2020 18:35:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '4e7008ee-8c83-4569-bffe-704f4f06dbf6' | System | 27 Sep 2020 18:35:54 |
| User entered '27 Sep 2020 13:35' | System | 27 Sep 2020 18:35:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 5' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-28T21:21:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586' | System | 29 Sep 2020 02:22:03 |
| User entered 'None (1)' | System | 29 Sep 2020 02:22:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586' | System | 29 Sep 2020 02:22:03 |
| User entered 'No (N)' | System | 29 Sep 2020 02:22:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:28', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586' | System | 29 Sep 2020 02:22:03 |
| User entered 'No (N)' | System | 29 Sep 2020 02:22:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-28T21:21:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586' | System | 29 Sep 2020 02:22:03 |
| User entered 'None (1)' | System | 29 Sep 2020 02:22:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:21:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0f37ede2-fd09-4e45-96d4-5d9dd8213586' | System | 29 Sep 2020 02:22:03 |
| User entered '28 Sep 2020 21:21' | System | 29 Sep 2020 02:22:03 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 6' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-29T12:54:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4' | System | 29 Sep 2020 17:55:18 |
| User entered 'None (1)' | System | 29 Sep 2020 17:55:18 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4' | System | 29 Sep 2020 17:55:18 |
| User entered 'No (N)' | System | 29 Sep 2020 17:55:18 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:54:59', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4' | System | 29 Sep 2020 17:55:18 |
| User entered 'No (N)' | System | 29 Sep 2020 17:55:18 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-29T12:55:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4' | System | 29 Sep 2020 17:55:18 |
| User entered 'None (1)' | System | 29 Sep 2020 17:55:18 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2cb8bb68-9d8d-430b-8156-e664ccdc9bd4' | System | 29 Sep 2020 17:55:18 |
| User entered '29 Sep 2020 12:55' | System | 29 Sep 2020 17:55:18 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 7' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-30T14:24:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038' | System | 30 Sep 2020 19:24:54 |
| User entered 'None (1)' | System | 30 Sep 2020 19:24:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038' | System | 30 Sep 2020 19:24:54 |
| User entered 'No (N)' | System | 30 Sep 2020 19:24:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038' | System | 30 Sep 2020 19:24:54 |
| User entered 'No (N)' | System | 30 Sep 2020 19:24:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-30T14:24:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038' | System | 30 Sep 2020 19:24:54 |
| User entered 'None (1)' | System | 30 Sep 2020 19:24:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'da6c4a21-41f6-47fd-b210-2a5e7f2b3038' | System | 30 Sep 2020 19:24:54 |
| User entered '30 Sep 2020 14:24' | System | 30 Sep 2020 19:24:54 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered 'None (0)' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered 'None (0)' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered 'None (0)' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:22:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered 'None (0)' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:23:02', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered 'None (0)' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:23:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered 'None (0)' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-24T10:24:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered 'No (N)' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T10:24:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '1a0bdaf9-f376-4daf-b689-0fe069c9f674' | System | 24 Sep 2020 15:24:45 |
| User entered '24 Sep 2020 10:24' | System | 24 Sep 2020 15:24:45 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 10:06' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 12:36' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 1, after vaccination (at home)' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered 'None (0)' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered 'None (0)' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:27:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered 'None (0)' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered 'None (0)' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:08', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered 'None (0)' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:15', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered 'None (0)' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-24T20:28:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered 'No (N)' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-24T20:28:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '428d8eb4-dfcc-4cb4-8274-1d09efaca604' | System | 25 Sep 2020 01:28:37 |
| User entered '24 Sep 2020 20:28' | System | 25 Sep 2020 01:28:37 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Sep 2020 13:31' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 2' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:09', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered 'None (0)' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered 'None (0)' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:16', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered 'None (0)' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered 'None (0)' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered 'None (0)' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered 'None (0)' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-25T12:43:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered 'No (N)' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-25T12:43:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '42186fc9-c0c4-42f7-89a6-6f3aa36c50b8' | System | 25 Sep 2020 17:43:58 |
| User entered '25 Sep 2020 12:43' | System | 25 Sep 2020 17:43:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 3' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered 'None (0)' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered 'None (0)' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:38', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered 'None (0)' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:08:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered 'None (0)' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:09:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered 'None (0)' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:09:11', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered 'None (0)' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-26T14:09:21', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered 'No (N)' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-26T14:09:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2edec182-8f14-4d2e-8f48-d8c6a4277424' | System | 26 Sep 2020 19:09:30 |
| User entered '26 Sep 2020 14:09' | System | 26 Sep 2020 19:09:30 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 4' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered 'None (0)' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:35:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered 'None (0)' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:02', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered 'None (0)' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered 'None (0)' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered 'None (0)' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered 'None (0)' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-27T13:36:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered 'No (N)' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-27T13:36:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '738881f8-754e-4b05-9351-054a82e9b90f' | System | 27 Sep 2020 18:36:29 |
| User entered '27 Sep 2020 13:36' | System | 27 Sep 2020 18:36:29 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 5' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered 'None (0)' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered 'None (0)' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered 'None (0)' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:22', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered 'None (0)' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered 'None (0)' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered 'None (0)' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-28T21:22:40', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered 'No (N)' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-28T21:22:47', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eb3fbf16-6352-4545-a02a-22e7d49c194a' | System | 29 Sep 2020 02:22:52 |
| User entered '28 Sep 2020 21:22' | System | 29 Sep 2020 02:22:52 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 6' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:21', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered 'None (0)' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered 'None (0)' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered 'None (0)' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered 'None (0)' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered 'None (0)' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:47', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered 'None (0)' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-29T12:55:52', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered 'No (N)' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-29T12:55:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a1162b92-43a8-4c05-ba17-5a133ec500c9' | System | 29 Sep 2020 17:55:58 |
| User entered '29 Sep 2020 12:55' | System | 29 Sep 2020 17:55:58 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 24 Sep 2020 15:02:57 |
| User entered 'Day 7' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:24:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered 'None (0)' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered 'None (0)' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:05', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered 'None (0)' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered 'None (0)' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered 'None (0)' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:21', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered 'None (0)' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 (d6510f5652d2da33)', Time: '2020-09-30T14:25:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered 'No (N)' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d6510f5652d2da33)', Time: '2020-09-30T14:25:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '677a36e5-b6b8-4303-8f63-f2333358e828' | System | 30 Sep 2020 19:25:35 |
| User entered '30 Sep 2020 14:25' | System | 30 Sep 2020 19:25:35 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '30 Sep 2020 12:00' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '01 Oct 2020 11:59' | System | 24 Sep 2020 15:02:57 |

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Oct 2020 15:51:38 |
| | | |

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '01 Oct 2020' | (b) (4), (b) (6) | 08 Oct 2020 15:51:38 |
| | | |

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 08 Oct 2020 15:51:38 |

US3362285

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 08 Oct 2020 15:51:38 |
| | | |

US3362285

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Oct 2020 15:51:42 |
| | | |

US3362285

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 08 Oct 2020 15:51:42 |

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Oct 2020 15:55:45 |
| | | |

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '08 Oct 2020' | (b) (4), (b) (6) | 08 Oct 2020 15:55:45 |
| | | |

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 08 Oct 2020 15:55:45 |

US3362285

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 08 Oct 2020 15:55:45 |
| | | |

US3362285

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Oct 2020 15:55:50 |
| | | |

US3362285

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 08 Oct 2020 15:55:50 |

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Oct 2020 13:57:46 |

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '15 Oct 2020' | (b) (4), (b) (6) | 15 Oct 2020 13:57:46 |
| | | |

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 15 Oct 2020 13:57:46 |

US3362285

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 15 Oct 2020 13:57:46 |

US3362285

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 15 Oct 2020 13:57:51 |
| | | |

US3362285

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 15 Oct 2020 13:57:51 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 16:17:16 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 22 Oct 2020 16:17:16 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 22 Oct 2020 16:17:16 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT2' | System | 22 Oct 2020 16:17:16 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '08:00' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 08:00' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered '36.7' C | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '82' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '16' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '136' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '88' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:00:45

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User closed query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 15:12:28 |
| Query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' answered with 'post dose time updated' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 18:54:01 |
| User entered '10:22' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Oct 2020 18:53:50 |
| User opened query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 18:28:51 |
| User entered '09:00' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 10:22' | System | 30 Oct 2020 18:53:50 |
| User entered '22 Oct 2020 09:00' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered '36.5' C | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '79' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '18' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '140' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '76' | (b) (4), (b) (6) | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:00:45

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 22 Oct 2020 16:19:36 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Was the physical examination performed?

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 16:20:55 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 22 Oct 2020 16:20:55 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 14:11:25 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Oct 2020 14:11:25 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Oct 2020 14:11:25 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------|----------------------|
| User entered 'MRNA-1273 OR PLACEBO' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 22 Oct 2020 14:11:25 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '08:42' | (b) (4), (b) (6) | 22 Oct 2020 14:11:25 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 08:42' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------------------|------------------|----------------------|
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 22 Oct 2020 14:11:25 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'ONCE' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:00:45

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'INTRAMUSCULAR' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 16:21:20 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 22 Oct 2020 16:21:20 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '08:11' | (b) (4), (b) (6) | 22 Oct 2020 16:21:20 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 08:11' | System | 22 Oct 2020 16:21:20 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:00:45

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '22 Oct 2020' | (b) (4), (b) (6) | 22 Oct 2020 16:22:04 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 22 Oct 2020 16:22:04 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 16:22:04 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '08:10' | (b) (4), (b) (6) | 22 Oct 2020 16:22:04 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 08:10' | System | 22 Oct 2020 16:22:04 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 22 Oct 2020 16:22:04 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 22 Oct 2020 16:22:04 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 22 Oct 2020 16:22:04 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Oct 2020 16:22:04 |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 22 Oct 2020 16:22:10 |
| | | |

US3362285

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Oct 2020 16:22:10 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:15:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102' | System | 22 Oct 2020 14:16:14 |
| User entered 'Yes (Y)' | System | 22 Oct 2020 14:16:14 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:15:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102' | System | 22 Oct 2020 14:16:14 |
| User entered '97.8' | System | 22 Oct 2020 14:16:14 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:15:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102' | System | 22 Oct 2020 14:16:14 |
| User entered 'No (N)' | System | 22 Oct 2020 14:16:14 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T09:16:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'e7373fcd-91ec-4806-a66c-228519b89102' | System | 22 Oct 2020 14:16:14 |
| User entered '22 Oct 2020 09:16' | System | 22 Oct 2020 14:16:14 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 09:02' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 11:32' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd' | System | 22 Oct 2020 18:58:38 |
| User entered 'Yes (Y)' | System | 22 Oct 2020 18:58:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:15', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd' | System | 22 Oct 2020 18:58:38 |
| User entered '97.3' | System | 22 Oct 2020 18:58:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd' | System | 22 Oct 2020 18:58:38 |
| User entered 'No (N)' | System | 22 Oct 2020 18:58:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ec11a26d-6f13-4d36-810c-7f19b4f8f3fd' | System | 22 Oct 2020 18:58:38 |
| User entered '22 Oct 2020 13:58' | System | 22 Oct 2020 18:58:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 12:27' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 2' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1' | System | 23 Oct 2020 17:30:44 |
| User entered 'Yes (Y)' | System | 23 Oct 2020 17:30:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1' | System | 23 Oct 2020 17:30:44 |
| User entered '98.0' | System | 23 Oct 2020 17:30:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1' | System | 23 Oct 2020 17:30:44 |
| User entered 'No (N)' | System | 23 Oct 2020 17:30:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:30:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed162228-ba13-48aa-9009-2cc2219cb0d1' | System | 23 Oct 2020 17:30:44 |
| User entered '23 Oct 2020 12:30' | System | 23 Oct 2020 17:30:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 3' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:28', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a' | System | 24 Oct 2020 17:17:01 |
| User entered 'Yes (Y)' | System | 24 Oct 2020 17:17:01 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a' | System | 24 Oct 2020 17:17:01 |
| User entered '97.7' | System | 24 Oct 2020 17:17:01 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a' | System | 24 Oct 2020 17:17:01 |
| User entered 'No (N)' | System | 24 Oct 2020 17:17:01 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:16:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '5c043a53-0bcf-474a-8d74-63e35adf659a' | System | 24 Oct 2020 17:17:01 |
| User entered '24 Oct 2020 12:16' | System | 24 Oct 2020 17:17:01 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 4' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d' | System | 25 Oct 2020 18:39:30 |
| User entered 'Yes (Y)' | System | 25 Oct 2020 18:39:30 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d' | System | 25 Oct 2020 18:39:30 |
| User entered '96.0' | System | 25 Oct 2020 18:39:30 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d' | System | 25 Oct 2020 18:39:30 |
| User entered 'No (N)' | System | 25 Oct 2020 18:39:30 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '342f3569-6197-4be3-8e03-df6844e5900d' | System | 25 Oct 2020 18:39:30 |
| User entered '25 Oct 2020 13:39' | System | 25 Oct 2020 18:39:30 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 5' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:44:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21' | System | 26 Oct 2020 19:45:17 |
| User entered 'Yes (Y)' | System | 26 Oct 2020 19:45:17 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:01', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21' | System | 26 Oct 2020 19:45:17 |
| User entered '96.3' | System | 26 Oct 2020 19:45:17 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21' | System | 26 Oct 2020 19:45:17 |
| User entered 'No (N)' | System | 26 Oct 2020 19:45:17 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:13', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '645d5316-1afb-4304-995c-e644e9836a21' | System | 26 Oct 2020 19:45:17 |
| User entered '26 Oct 2020 14:45' | System | 26 Oct 2020 19:45:17 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 6' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:17', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a' | System | 27 Oct 2020 17:55:44 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 17:55:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a' User entered '97.2' | System | 27 Oct 2020 17:55:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a' | System | 27 Oct 2020 17:55:44 |
| User entered 'No (N)' | System | 27 Oct 2020 17:55:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:55:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '021a0c7b-b86b-417d-8c95-93e11b70372a' | System | 27 Oct 2020 17:55:44 |
| User entered '27 Oct 2020 12:55' | System | 27 Oct 2020 17:55:44 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 7' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d' | System | 29 Oct 2020 19:11:58 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 19:11:58 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d' | System | 29 Oct 2020 19:11:58 |
| User entered '97.3' | System | 29 Oct 2020 19:11:58 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d' | System | 29 Oct 2020 19:11:58 |
| User entered 'No (N)' | System | 29 Oct 2020 19:11:58 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:46:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2ffecb6c-cd0c-450d-806f-8aac578d211d' | System | 29 Oct 2020 19:11:58 |
| User entered '28 Oct 2020 17:46' | System | 29 Oct 2020 19:11:58 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 09:02' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 11:32' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-22T13:58:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08' | System | 22 Oct 2020 18:59:23 |
| User entered 'None (1)' | System | 22 Oct 2020 18:59:23 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:58:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08' | System | 22 Oct 2020 18:59:23 |
| User entered 'No (N)' | System | 22 Oct 2020 18:59:23 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08' | System | 22 Oct 2020 18:59:23 |
| User entered 'No (N)' | System | 22 Oct 2020 18:59:23 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-22T13:59:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08' | System | 22 Oct 2020 18:59:23 |
| User entered 'None (1)' | System | 22 Oct 2020 18:59:23 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:18', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'c9344769-c24b-48c4-98c9-946181ad4e08' | System | 22 Oct 2020 18:59:23 |
| User entered '22 Oct 2020 13:59' | System | 22 Oct 2020 18:59:23 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 12:27' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 2' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-23T12:30:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1' | System | 23 Oct 2020 17:31:36 |
| User entered 'None (1)' | System | 23 Oct 2020 17:31:36 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1' | System | 23 Oct 2020 17:31:36 |
| User entered 'No (N)' | System | 23 Oct 2020 17:31:36 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:16', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1' | System | 23 Oct 2020 17:31:36 |
| User entered 'No (N)' | System | 23 Oct 2020 17:31:36 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-23T12:31:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1' | System | 23 Oct 2020 17:31:36 |
| User entered 'None (1)' | System | 23 Oct 2020 17:31:36 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb92c1b6-7cf0-4c9e-9f7c-cb51456de8d1' | System | 23 Oct 2020 17:31:36 |
| User entered '23 Oct 2020 12:31' | System | 23 Oct 2020 17:31:36 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 3' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-24T12:17:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf' | System | 24 Oct 2020 17:17:39 |
| User entered 'None (1)' | System | 24 Oct 2020 17:17:39 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:11', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf' | System | 24 Oct 2020 17:17:39 |
| User entered 'No (N)' | System | 24 Oct 2020 17:17:39 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf' | System | 24 Oct 2020 17:17:39 |
| User entered 'No (N)' | System | 24 Oct 2020 17:17:39 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-24T12:17:30', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf' | System | 24 Oct 2020 17:17:39 |
| User entered 'None (1)' | System | 24 Oct 2020 17:17:39 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '584cea1f-da7d-45c2-ad96-82f4ecdf15bf' | System | 24 Oct 2020 17:17:39 |
| User entered '24 Oct 2020 12:17' | System | 24 Oct 2020 17:17:39 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 4' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-25T13:39:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438' | System | 25 Oct 2020 18:40:04 |
| User entered 'None (1)' | System | 25 Oct 2020 18:40:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438' | System | 25 Oct 2020 18:40:04 |
| User entered 'No (N)' | System | 25 Oct 2020 18:40:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:39:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438' | System | 25 Oct 2020 18:40:04 |
| User entered 'No (N)' | System | 25 Oct 2020 18:40:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-25T13:39:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438' | System | 25 Oct 2020 18:40:04 |
| User entered 'None (1)' | System | 25 Oct 2020 18:40:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'a5b3cc19-5a90-4db5-8d08-9a3e7cd9a438' | System | 25 Oct 2020 18:40:04 |
| User entered '25 Oct 2020 13:40' | System | 25 Oct 2020 18:40:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 5' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-26T14:45:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e' | System | 26 Oct 2020 19:45:41 |
| User entered 'None (1)' | System | 26 Oct 2020 19:45:41 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:25', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e' | System | 26 Oct 2020 19:45:41 |
| User entered 'No (N)' | System | 26 Oct 2020 19:45:41 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:28', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e' | System | 26 Oct 2020 19:45:41 |
| User entered 'No (N)' | System | 26 Oct 2020 19:45:41 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-26T14:45:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e' | System | 26 Oct 2020 19:45:41 |
| User entered 'None (1)' | System | 26 Oct 2020 19:45:41 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:36', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'd63aa4a0-0f40-438a-bf2f-706ad650d83e' | System | 26 Oct 2020 19:45:41 |
| User entered '26 Oct 2020 14:45' | System | 26 Oct 2020 19:45:41 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 6' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 (1db0398f97ba671b)', Time: '2020-10-27T12:55:58', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524' | System | 27 Oct 2020 17:57:26 |
| User entered 'None (1)' | System | 27 Oct 2020 17:57:26 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:56:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524' | System | 27 Oct 2020 17:57:26 |
| User entered 'No (N)' | System | 27 Oct 2020 17:57:26 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:56:48', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524' | System | 27 Oct 2020 17:57:26 |
| User entered 'No (N)' | System | 27 Oct 2020 17:57:26 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 (1db0398f97ba671b)', Time: '2020-10-27T12:57:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524' | System | 27 Oct 2020 17:57:26 |
| User entered 'None (1)' | System | 27 Oct 2020 17:57:26 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:12', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'eea7ff2c-3a0b-4347-bec6-16419e18a524' | System | 27 Oct 2020 17:57:26 |
| User entered '27 Oct 2020 12:57' | System | 27 Oct 2020 17:57:26 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 7' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 (1db0398f97ba671b)', Time: '2020-10-28T17:47:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc' | System | 29 Oct 2020 19:12:00 |
| User entered 'None (1)' | System | 29 Oct 2020 19:12:00 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc' | System | 29 Oct 2020 19:12:00 |
| User entered 'No (N)' | System | 29 Oct 2020 19:12:00 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:14', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc' | System | 29 Oct 2020 19:12:00 |
| User entered 'No (N)' | System | 29 Oct 2020 19:12:00 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 (1db0398f97ba671b)', Time: '2020-10-28T17:47:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc' | System | 29 Oct 2020 19:12:00 |
| User entered 'None (1)' | System | 29 Oct 2020 19:12:00 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '3d3877a2-4805-4e1d-9a0e-67f7294742dc' | System | 29 Oct 2020 19:12:00 |
| User entered '28 Oct 2020 17:47' | System | 29 Oct 2020 19:12:00 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 09:02' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 11:32' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 1, after vaccination (at home)' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered 'None (0)' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered 'None (0)' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered 'None (0)' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered 'None (0)' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:53', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered 'None (0)' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T13:59:56', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered 'None (0)' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-22T14:00:03', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered 'No (N)' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-22T14:00:06', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '2e80c378-5f13-475a-a2b2-5bc77b7578a6' | System | 22 Oct 2020 19:00:11 |
| User entered '22 Oct 2020 14:00' | System | 22 Oct 2020 19:00:11 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '22 Oct 2020 12:27' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 2' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:31:57', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered 'None (0)' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered 'No interference with activity (1)' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:29', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered 'None (0)' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered 'None (0)' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered 'None (0)' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:32:43', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered 'None (0)' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-23T12:32:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered 'No (N)' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-23T12:33:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'ed080af1-5b0f-4ded-807a-259d90757e8d' | System | 23 Oct 2020 17:33:04 |
| User entered '23 Oct 2020 12:33' | System | 23 Oct 2020 17:33:04 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '23 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 3' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:44', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered 'None (0)' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:47', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered 'None (0)' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:51', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered 'None (0)' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:17:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered 'None (0)' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:18:00', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered 'None (0)' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:18:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered 'None (0)' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-24T12:18:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered 'No (N)' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-24T12:18:24', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: 'bb53b116-3b6d-4235-bb51-c6a22dfe7665' | System | 24 Oct 2020 17:18:32 |
| User entered '24 Oct 2020 12:18' | System | 24 Oct 2020 17:18:32 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 4' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:15', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered 'None (0)' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:19', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered 'None (0)' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered 'None (0)' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:27', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered 'None (0)' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:32', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered 'None (0)' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:35', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered 'None (0)' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-25T13:40:39', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered 'No (N)' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-25T13:40:50', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '36cf83dc-a458-4033-8e14-9f08263bc26e' | System | 25 Oct 2020 18:40:55 |
| User entered '25 Oct 2020 13:40' | System | 25 Oct 2020 18:40:55 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '25 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 5' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered 'None (0)' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:45', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered 'None (0)' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered 'None (0)' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:52', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered 'None (0)' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered 'None (0)' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:45:59', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered 'None (0)' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

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 (00547c1d73c71098)', Time: '2020-10-26T14:46:04', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered 'No (N)' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (00547c1d73c71098)', Time: '2020-10-26T14:46:10', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '9ee83f1a-a287-4bb2-b26d-4230366d66ad' | System | 26 Oct 2020 19:46:15 |
| User entered '26 Oct 2020 14:46' | System | 26 Oct 2020 19:46:15 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '26 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 6' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:20', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered 'None (0)' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:23', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered 'None (0)' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:26', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered 'None (0)' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:33', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered 'None (0)' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:42', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered 'None (0)' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:57:44', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered 'None (0)' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

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 (1db0398f97ba671b)', Time: '2020-10-27T12:59:31', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered 'No (N)' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-27T12:59:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '0fcd30d3-d708-4d90-a4d0-a01d2b4577a6' | System | 27 Oct 2020 17:59:38 |
| User entered '27 Oct 2020 12:59' | System | 27 Oct 2020 17:59:38 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|--------|----------------------|
| Data entry locked. | System | 22 Oct 2020 14:11:25 |
| User entered 'Day 7' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

HEADACHE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:34', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered 'None (0)' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

FATIGUE

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:37', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered 'None (0)' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:41', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered 'None (0)' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:46', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered 'None (0)' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:49', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered 'None (0)' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

CHILLS

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:47:55', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered 'None (0)' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

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 (1db0398f97ba671b)', Time: '2020-10-28T17:48:03', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered 'No (N)' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1db0398f97ba671b)', Time: '2020-10-28T17:48:07', User OID: 'PatientReportedOutcome (US3362285)', ODM File OID: '59121783-9f11-418c-96ea-1eee7c780a50' | System | 29 Oct 2020 19:11:59 |
| User entered '28 Oct 2020 17:48' | System | 29 Oct 2020 19:11:59 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '28 Oct 2020 12:00' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:00:45

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '29 Oct 2020 11:59' | System | 22 Oct 2020 14:11:25 |

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 29 Oct 2020 22:00:42 |
| | | |

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '29 Oct 2020' | (b) (4), (b) (6) | 29 Oct 2020 22:00:42 |
| | | |

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 29 Oct 2020 22:00:42 |
| | | |

US3362285

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 29 Oct 2020 22:00:42 |
| | | |

US3362285

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Nov 2020 17:47:42 |
| | | |

US3362285

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 17:47:42 |

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Nov 2020 17:52:41 |
| | | |

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '05 Nov 2020' | (b) (4), (b) (6) | 05 Nov 2020 17:52:41 |
| | | |

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 05 Nov 2020 17:52:41 |

US3362285

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 05 Nov 2020 17:52:41 |

US3362285

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Nov 2020 17:52:46 |
| | | |

US3362285

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Nov 2020 17:52:46 |

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Nov 2020 19:47:56 |
| | | |

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '12 Nov 2020' | (b) (4), (b) (6) | 12 Nov 2020 19:47:56 |
| | | |

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 12 Nov 2020 19:47:56 |

US3362285

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:00:45

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 12 Nov 2020 19:47:56 |
| | | |

US3362285

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 12 Nov 2020 19:47:45 |
| | | |

US3362285

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 12 Nov 2020 19:47:45 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 15:25:06 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '16 Nov 2020' | (b) (4), (b) (6) | 16 Nov 2020 15:25:06 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 16 Nov 2020 15:25:06 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:00:45

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT3' | System | 16 Nov 2020 15:25:06 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '16 Nov 2020' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '07:42' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '16 Nov 2020 07:42' | System | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered '36.6' C | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '89' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '18' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '139' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '72' | (b) (4), (b) (6) | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:00:45

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 16 Nov 2020 15:55:00 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 15:55:40 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:00:45

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '16 Nov 2020' | (b) (4), (b) (6) | 16 Nov 2020 15:55:40 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 15:57:05 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '16 Nov 2020' | (b) (4), (b) (6) | 16 Nov 2020 15:57:05 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| User entered '07:55' | (b) (4), (b) (6) | 16 Nov 2020 15:57:05 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '16 Nov 2020 07:55' | System | 16 Nov 2020 15:57:05 |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 16 Nov 2020 15:57:13 |
| | | |

US3362285

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:00:45

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 16 Nov 2020 15:57:13 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '29 Oct 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '02 Nov 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '05 Nov 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '09 Nov 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '12 Nov 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '16 Nov 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '19 Nov 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '23 Nov 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '26 Nov 2022 00:01' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:00:45

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 10:34:03 |
| Amendment Manager: User entered '30 Nov 2022 23:59' | System | 20 Nov 2020 10:34:03 |

US3362285

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:00:45

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 20 Nov 2020 20:22:11 |
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:26 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[AEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:39 |
| User entered 'USA-US112-2020-mRNA-1273-P301000011' | System | 24 Nov 2020 00:22:32 |
| User entered 'New' | (b) (4), (b) (6) | 24 Nov 2020 00:22:32 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Nov 2020 20:29:14 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 20 Nov 2020 20:29:14 |
| Data point term sent to Coder | System | 20 Nov 2020 20:28:37 |
| User entered 'Cerebrovascular Accident' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

Start date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Nov 2020' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Nov 2020' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Severity](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User entered 'Grade 4 (Grade 4)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Death](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '1' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered 'I' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '16 Nov 2020' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '18 Nov 2020' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|-----------------------|-----------------------------------|----------------------|
| User entered 'No (N)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Other medically important event](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Not Related (NOT RELATED)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[None](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered 'I' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User entered 'Patient contacted site -sent to ER on night of 16Nov2020 for difficulty speaking and diagnosed with cerebrovascular accident. admitted to hospital 16Nov-18Nov2020; stated only new medication was full dose Asprin 325mg right now; will come to sign medical release and update accordingly, has follow up with cardiologist reports cause of CVA left coronary artery occlusion - will confirm with medical records.' | Crystal Rowell (b) (4) (b) (4) | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Nov 2020 20:28:37 |

US3362285

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:00:45

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 20 Nov 2020 20:28:37 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:00:45

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:19:55 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:19:55 |
| Data point term sent to Coder | System | 30 Sep 2020 15:18:56 |
| User entered 'LOSARTAN/HYDROCHLOROTHIAZIDE' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------|----------------------|
| User entered 'HYPERTENSION' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered '100/25' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2001' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:17:58 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:19:54 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:19:54 |
| Data point term sent to Coder | System | 30 Sep 2020 15:18:57 |
| User entered 'ZETIA' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------|----------------------|
| User entered 'HYPERLIPIDEMIA' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '10' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:18:43 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:18:43 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 15:20:56 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 15:20:56 |
| Data point term sent to Coder | System | 30 Sep 2020 15:19:58 |
| User entered 'GLIPIZIDE' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| User entered 'DIABETES TYPE II' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '4' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| User entered 'twice daily (BID)' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2001' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:19:33 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: DULAGLUTIDE, PRODUCTSYNONYM: TRULICITY - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 15:21:56 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 15:21:56 |
| Data point term sent to Coder | System | 30 Sep 2020 15:21:00 |
| User entered 'TRULICITY' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| User entered 'DIABETES TYPE II' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '1.5' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'every week (QS)' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '803 (803)' | System | 30 Sep 2020 15:20:38 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 15:22:54 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Sep 2020 15:22:54 |
| Data point term sent to Coder | System | 30 Sep 2020 15:22:04 |
| User entered 'JARDIANCE' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| User entered 'DIABETES TYPE II' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '25' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN Sep 2020' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:21:21 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:23:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:23:48 |
| Data point term sent to Coder | System | 30 Sep 2020 15:23:06 |
| User entered 'TAMSULOSIN' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'BENIGN PROSTATE HYPERTROPHY' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '0.4' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:22:13 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:23:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:23:49 |
| Data point term sent to Coder | System | 30 Sep 2020 15:23:07 |
| User entered 'FINASTERIDE' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User entered 'BENIGN PROSTATE HYPERTROPHY' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '5' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2013' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:22:54 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[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: OXICAMS, PRODUCT: MELOXICAM, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:36:56 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:36:56 |
| Data point term sent to Coder | System | 30 Sep 2020 15:25:13 |
| User entered 'MOBIC' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'ANXIETY' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '15' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:24:57 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:27:50 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 15:27:50 |
| Data point term sent to Coder | System | 30 Sep 2020 15:26:14 |
| User entered 'ASPIRIN' | (b) (4), (b) (6) (b) (4) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------|----------------------|
| User entered 'CARDIAC HEALTH' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| User entered '81' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mg (mg)' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------|----------------------|
| User entered 'once daily (QD)' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'UN UNK 2018' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 30 Sep 2020 15:25:31 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Nov 2020 16:39:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Nov 2020 16:39:49 |
| Data point term sent to Coder | System | 13 Nov 2020 16:38:33 |
| User entered 'INFLUENZA VACCINE' | (b) (4), (b) (6) (b) (4) | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| User entered 'INFLUENZA PREVENTION' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '0.5' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mL (mL)' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '11 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '11 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:37:41 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Nov 2020 16:39:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Nov 2020 16:39:51 |
| Data point term sent to Coder | System | 13 Nov 2020 16:38:33 |
| User entered 'PNEUMONIA VACCINE' | (b) (4), (b) (6) (b) (4) | 13 Nov 2020 16:38:28 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| User entered 'PNEUMONIA PREVENTION' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| User entered '0.5' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| User entered 'mL (mL)' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '11 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| User entered '11 Nov 2020' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |
| | | |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 13 Nov 2020 16:38:28 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:38:28 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:38:28 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 13 Nov 2020 16:38:28 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 23:52:11 |
| User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 23:52:11 |
| Data point term sent to Coder | System | 24 Nov 2020 21:51:55 |
| User entered 'clopidogrel' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User entered 'prevention of cerebrovascular accident' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Dose per administration](#)

| Audit | User | Time (GMT) |
|-------------------|-----------------------------------|----------------------|
| User entered '75' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'mg (mg)' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User entered 'once daily (QD)' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered 'Oral (ORAL)' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User entered '24 Nov 2020' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|------------------|-----------------------------------|----------------------|
| User entered '0' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Ongoing?](#)

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------|-----------------------------------|----------------------|
| User entered empty. | Crystal Rowell (b) (4) (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User closed query 'Data is required. Please complete.' (Site from System). | System | 24 Nov 2020 22:18:31 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 24 Nov 2020 22:18:31 |
| User entered 'No (N)' reason for change: Data Entry Error | Crystal Rowell (b) (4) | 24 Nov 2020 22:18:31 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 24 Nov 2020 21:51:30 |
| User entered empty. | Crystal Rowell (b) (4) | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:00:45

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 24 Nov 2020 21:51:30 |

US3362285

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:00:45

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Sep 2020 15:16:42 |
| | | |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'USA-US112-2020-MRNA-1273-P301000011' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Yes (Y)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Yes (Y)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Yes (Y)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Jordan' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Whatley' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered '5326 O'donovan dr' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'baton rouge' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered '70808' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Investigator Country](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered 'US' | System | 24 Nov 2020 00:23:02 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 00:23:02 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[SAEID](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'USA-US112-2020-MRNA-1273-P301000011' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

Serious

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Yes (Y)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Death](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Life threatening](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Yes (Y)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Yes (Y)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Other medically important event](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'No (N)' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Jordan' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'Whatley' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered '5326 O'donovan dr' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered 'baton rouge' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 24 Nov 2020 00:22:55 |
| User entered '70808' | System | 24 Nov 2020 00:22:32 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[Investigator Country](#)

| Audit | User | Time (GMT) |
|-------------------|--------|----------------------|
| User entered 'US' | System | 24 Nov 2020 00:23:02 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 26 Nov 2020 11:00:45

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 00:23:02 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:45

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '24/Nov/2020 00:23' | System | 24 Nov 2020 00:23:02 |

US3362285

Folder: SAE USA-US112-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:00:45

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) | 24 Nov 2020 00:23:02 |