

US3242264 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:12:49

All time stamps listed in this document are displayed in GMT

US3242264

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Participant ID

US3242264

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

US3242264

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 01 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 |
|------------|------|

US3242264

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1971 |
| Age | 49 |
| Age Units | YEARS |
| Age (Derived) | 49 |
| 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 | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 1 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

Data signed: (b) (4) 12 Feb 2021 18:20:54

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:20:54

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|---|--|
| Condition | HYPERTENSION |
| 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 (2)

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|---|--|
| Condition | HYPERLIPIDEMIA |
| Start date (dd MMM yyyy) | UN UNK 2017 |
| 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 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|---|--|
| Condition | HYPOTHYROIDISM |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|---|--|
| Condition | BACK PAIN |
| Start date (dd MMM yyyy) | UN UNK 1990 |
| 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 1990 |
| Start Year (derived) | 1990 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|---|--|
| Condition | VASECTOMY |
| Start date (dd MMM yyyy) | UN UNK 1995 |
| 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 1995 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1995 |
| Start Year (derived) | 1995 |
| Stop Month and Year (derived) | JAN 1995 |
| Stop Year (derived) | 1995 |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 1 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:03 (24 HR) |
| Vital Signs Date and Time (derived) | 1 SEP 2020 09:03 |
| Height (xxx.x) | 72 in |
| Weight (xxx.x) | 216 lb |
| BMI (xxx.x) | 29.35612 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:20:54

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

VOLUNTEERS WITH
HOMELESS-PROVIDES MEALS
AND SOFTBALL COACH

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:20:54

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| | |
|--|-------|
| Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| Resides in high density housing (e.g., high rise apartments with shared entrances or elevators) | True |
| 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) | False |
| Other | False |
| Specify | |

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 1 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

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110115

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 18:20:55

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|--|
| 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) | 1 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:18 (24 HR) |
| Vital Signs Date and Time (derived) | 1 SEP 2020 09:18 |
| Temperature (xxx.x) | 98.0 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 114 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|--|
| 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) | 1 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:53 (24 HR) |
| Vital Signs Date and Time (derived) | 1 SEP 2020 10:53 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 60 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 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

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 SEP 2020

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

Treatment Date and Time (derived) 1 SEP 2020 10:23

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 1 SEP 2020

Collection time (00:00-23:59) 10:07 (24 HR)

Collection date and time (derived) 1 SEP 2020 10:07

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| Collection date (dd MMM yyyy) | | | 1 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:03 | 1 SEP 2020 10:03 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

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: 09 Jun 2021 16:12:49

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

98.3 °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

01 SEP 2020 11:00

PC Open Date & Time

01 SEP 2020 10:43

PC Close Date & Time

01 SEP 2020 13:13

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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 98.4 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 01 SEP 2020 14:10 |
| PC Open Date & Time | 01 SEP 2020 14:08 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

05 SEP 2020 09:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

05 SEP 2020 13:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 09:20

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

08 SEP 2020 09:57

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 11:01

PC Open Date & Time

01 SEP 2020 10:43

PC Close Date & Time

01 SEP 2020 13:13

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

01 SEP 2020 14:11

PC Open Date & Time

01 SEP 2020 14:08

PC Close Date & Time

02 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

02 SEP 2020 12:04

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

03 SEP 2020 12:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

05 SEP 2020 09:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

05 SEP 2020 13:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

07 SEP 2020 09:21

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

08 SEP 2020 09:58

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 01 SEP 2020 11:01 |
| PC Open Date & Time | 01 SEP 2020 10:43 |
| PC Close Date & Time | 01 SEP 2020 13:13 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 01 SEP 2020 14:12 |
| PC Open Date & Time | 01 SEP 2020 14:08 |
| PC Close Date & Time | 02 SEP 2020 11:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

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 ☒

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 SEP 2020 12:04 |
| PC Open Date & Time | 02 SEP 2020 12:00 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

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 ☒

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EAB) (1725)

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US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

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 ☒

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 09:36 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

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 ☒

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 13:08 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 09:21 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

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 ☒

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 09:58 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3242264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 28 SEP 2020 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT2 |
|------------|--------|

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:51 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 10:51 |
| Temperature (xxx.x) | 97.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 76 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 70 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 28 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:08 (24 HR) |
| Vital Signs Date and Time (derived) | 28 SEP 2020 12:08 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 112 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

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.

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 11:43 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 11:43

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

What was the frequency of the study treatment dosing? ONCE

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

US3242264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 28 SEP 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 11:43 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 28 SEP 2020 11:43 |
|------------------------------------|-------------------|

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 28 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:05 | 28 SEP 2020 11:05 |
| Nasopharyngeal Swab 2 | No | | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:55

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 12:13

PC Open Date & Time

28 SEP 2020 12:03

PC Close Date & Time

28 SEP 2020 14:33

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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 98.5 °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 | 29 SEP 2020 06:30 |
| PC Open Date & Time | 28 SEP 2020 15:28 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 15:11

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 14:35

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

01 OCT 2020 12:52

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

02 OCT 2020 13:09

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:01

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

05 OCT 2020 08:54

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 12:14

PC Open Date & Time

28 SEP 2020 12:03

PC Close Date & Time

28 SEP 2020 14:33

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

29 SEP 2020 06:30

PC Open Date & Time

28 SEP 2020 15:28

PC Close Date & Time

29 SEP 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 15:11

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 14:35

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

01 OCT 2020 12:52

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

02 OCT 2020 13:10

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 12:01

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

05 OCT 2020 08:55

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 28 SEP 2020 12:15 |
| PC Open Date & Time | 28 SEP 2020 12:03 |
| PC Close Date & Time | 28 SEP 2020 14:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 29 SEP 2020 06:31 |
| PC Open Date & Time | 28 SEP 2020 15:28 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

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 ☒

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

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 ☒

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 SEP 2020 14:37 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

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 ☒

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 01 OCT 2020 12:53 |
| PC Open Date & Time | 01 OCT 2020 12:00 |
| PC Close Date & Time | 02 OCT 2020 11:59 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 2271

EAB) (1725)

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 02 OCT 2020 13:10 |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2271

EAB) (1725)

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 OCT 2020 12:02 |
| PC Open Date & Time | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2271

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 OCT 2020 08:55 |
| PC Open Date & Time | 04 OCT 2020 12:00 |
| PC Close Date & Time | 05 OCT 2020 11:59 |

US3242264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:21:07

Generated On: 09 Jun 2021 16:12:49

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 26 OCT 2020 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT3 |
|------------|--------|

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:21:07

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 26 OCT 2020 |
| Time of assessment (00:00-23:59) | 11:44 (24 HR) |
| Vital Signs Date and Time (derived) | 26 OCT 2020 11:44 |
| Temperature (xxx.x) | 97.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:21:07

Generated On: 09 Jun 2021 16:12:49

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.

US3242264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:21:07

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 26 OCT 2020 |
| Collection time (00:00-23:59) | 12:14 (24 HR) |
| Collection date and time (derived) | 26 OCT 2020 12:14 |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:21:07

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 01 NOV 2020 00:02:29 |
| Patient Cloud Open Date & Time | 01 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 05 NOV 2020 23:59 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 16:21:35

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 00:07:11

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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 checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 23 NOV 2020 09:33:35 |
| Patient Cloud Open Date & Time | 19 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 23 NOV 2020 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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 checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you 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 checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 26 NOV 2020 00:04:18 |
| Patient Cloud Open Date & Time | 26 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 30 NOV 2020 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 DEC 2020 12:59:46 |
| Patient Cloud Open Date & Time | 03 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 07 DEC 2020 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 09:09:38

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 12:08:36

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 10:56:07

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 31 DEC 2020 00:13:49 |
| Patient Cloud Open Date & Time | 31 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 04 JAN 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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 checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 07 JAN 2021 00:01:46 |
| Patient Cloud Open Date & Time | 07 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 11 JAN 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 00:02:00

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| TIMEPOINT | DAY 145 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 21 JAN 2021 00:02:09 |
| Patient Cloud Open Date & Time | 21 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 25 JAN 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 00:01:57

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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 checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you 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 checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 04 FEB 2021 00:01:50 |
| Patient Cloud Open Date & Time | 04 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 08 FEB 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| | |
|---|--|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 11 FEB 2021 18:23:34 |
| Patient Cloud Open Date & Time | 11 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 15 FEB 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 19:25:57

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 03:39:50

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 08:47:59

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 MAR 2021 00:19:14 |
| Patient Cloud Open Date & Time | 11 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 15 MAR 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced 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 checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | True |
| Chills | True |
| Cough | False |
| Shortness of breath | False |
| Difficulty breathing | False |
| Fatigue | True |
| Muscle aches | False |
| Body aches | True |
| Headache | True |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | False |
| Vomiting | False |
| Diarrhea | False |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 18 MAR 2021 00:06:40 |
| Patient Cloud Open Date & Time | 18 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 22 MAR 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 00:56:24

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 00:43:37

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 10:56:56

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 02:00:39

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:02:35

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 09:19:48

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| TIMEPOINT | DAY 250 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 20 MAY 2021 00:01 |
| Patient Cloud Close Date & Time | 24 MAY 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 03 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 07 JUN 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 14 JUN 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 26 JUL 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐
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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 29 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 02 AUG 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 12 AUG 2021 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 16 AUG 2021 23:59 |
|---|-------------------|

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 30 AUG 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 06 SEP 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 16 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 20 SEP 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 30 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 04 OCT 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 14 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 18 OCT 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 02 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 06 DEC 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 09 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 13 DEC 2021 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 30 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 03 JAN 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 31 JAN 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 03 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 07 FEB 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| TIMEPOINT | DAY 530 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 MAR 2022 00:01 |
| Patient Cloud Close Date & Time | 14 MAR 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 25 APR 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| TIMEPOINT | DAY 649 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 09 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 13 JUN 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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="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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 18 AUG 2022 00:01 |
| Patient Cloud Close Date & Time | 22 AUG 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 25 AUG 2022 00:01 |
| Patient Cloud Close Date & Time | 29 AUG 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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 ☐
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 ☐

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 19 SEP 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 22 SEP 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 26 SEP 2022 23:59 |
|---|-------------------|

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 29 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 03 OCT 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 06 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 10 OCT 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 13 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 17 OCT 2022 23:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 27 OCT 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 31 OCT 2022 23:59 |
|---|-------------------|

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

| 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"/> |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3242264

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:12:49

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| Yes | No | 28 FEB 2021 08:05:06 |

US3242264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 22:07:21

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:07:21

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3242264

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

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.

US3242264

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

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

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

US3242264

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | |
|--|--|
| Date of Contact | 14 OCT 2020 |
| Time of Contact | 11:27 |
| Date and Time of Contact (derived) | 14 OCT 2020 11:27 |
| Type of Contact | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div> |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Symptom Day

| | |
|--------|----------------------------------|
| Day 1 | <input checked="" type="radio"/> |
| Day 2 | <input type="radio"/> |
| Day 3 | <input type="radio"/> |
| Day 4 | <input type="radio"/> |
| Day 5 | <input type="radio"/> |
| Day 6 | <input type="radio"/> |
| Day 7 | <input type="radio"/> |
| Day 8 | <input type="radio"/> |
| Day 9 | <input type="radio"/> |
| Day 10 | <input type="radio"/> |
| Day 11 | <input type="radio"/> |
| Day 12 | <input type="radio"/> |
| Day 13 | <input type="radio"/> |
| Day 14 | <input type="radio"/> |
| Day 15 | <input type="radio"/> |
| Day 16 | <input type="radio"/> |
| Day 17 | <input type="radio"/> |
| Day 18 | <input type="radio"/> |
| Day 19 | <input type="radio"/> |
| Day 20 | <input type="radio"/> |
| Day 21 | <input type="radio"/> |
| Day 22 | <input type="radio"/> |
| Day 23 | <input type="radio"/> |
| Day 24 | <input type="radio"/> |
| Day 25 | <input type="radio"/> |
| Day 26 | <input type="radio"/> |
| Day 27 | <input type="radio"/> |
| Day 28 | <input type="radio"/> |
| Day 29 | <input type="radio"/> |
| Day 30 | <input type="radio"/> |
| Day 31 | <input type="radio"/> |
| Day 32 | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 10 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input checked="" type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------|--------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |

| | |
|------|-------------|
| Date | 11 OCT 2020 |
|------|-------------|

| | |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

| | |
|---------------|---------------|
| O2 Saturation | ND - Not Done |
|---------------|---------------|

| | |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

| | |
|-------------|---------------|
| Temperature | ND - Not Done |
|-------------|---------------|

| | |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|-------|---------------------------------------|
| Cough | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |
| | Not Done <input type="radio"/> |

| | |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
| | Mild <input type="radio"/> |
| | Moderate <input type="radio"/> |
| | Severe <input type="radio"/> |

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EAB) (1725)

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Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input checked="" type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 12 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input checked="" type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 13 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input checked="" type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 14 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 99.9 F | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input checked="" type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 15 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 99.1 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input checked="" type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 16 OCT 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 100 % | |
| O2 Saturation Units | % | |
| Temperature | 98.4 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Date of Visit 14 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 14 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Mar 2021 22:07:21

Generated On: 09 Jun 2021 16:12:49

| Visit | Was Saliva Collected? | Date of Collection |
|--------|------------------------|--------------------|
| Day 3 | Yes | 16 OCT 2020 |
| Day 5 | NA (COVID-19 Negative) | |
| Day 7 | NA (COVID-19 Negative) | |
| Day 9 | NA (COVID-19 Negative) | |
| Day 14 | NA (COVID-19 Negative) | |
| Day 21 | NA (COVID-19 Negative) | |
| Day 28 | NA (COVID-19 Negative) | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 14 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 | SICKD1 |
|------------|--------|

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 14 OCT 2020 |
| Time of assessment (00:00-23:59) | 12:28 (24 HR) |
| Vital Signs Date and Time (derived) | 14 OCT 2020 12:28 |
| Height (xxx.x) | 72 in |
| Weight (xxx.x) | 216 lb |
| Temperature (xxx.x) | 98.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3242264

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 OCT 2020

US3242264

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 15 FEB 2021

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

Folder OID UNBLND_DECIDE

US3242264

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 16:07:14

Generated On: 09 Jun 2021 16:12:49

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 15 FEB 2021 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 15 FEB 2021 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3242264

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |

US3242264

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 FEB 2021 |
| Time of assessment (00:00-23:59) | 09:16 (24 HR) |
| Vital Signs Date and Time (derived) | 15 FEB 2021 09:16 |
| Temperature (xxx.x) | 97.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 72 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3242264

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 FEB 2021 |
| Time of assessment (00:00-23:59) | 10:02 (24 HR) |
| Vital Signs Date and Time (derived) | 15 FEB 2021 10:02 |
| Temperature (xxx.x) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 122 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3242264

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

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.

US3242264

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

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 15 FEB 2021

What was the treatment time? (00:00-23:59) 09:32 (24 HR)

Treatment Date and Time (derived) 15 FEB 2021 09:32

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

What was the frequency of the study treatment dosing? ONCE

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

US3242264

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 15 FEB 2021

Collection time (00:00-23:59) 08:56 (24 HR)

Collection date and time (derived) 15 FEB 2021 08:56

US3242264

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 15 FEB 2021 |
| Collection time (00:00 - 23:59) | 08:53 |
| Collection Date and Time (derived) | 15 FEB 2021 08:53 |

US3242264

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

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 17:23:10

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 22:07:21

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:07:21

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 16:07:14

Generated On: 09 Jun 2021 16:12:49

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 15 MAR 2021 |
|--------------------------|-------------|

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

| | |
|------------|-------|
| Folder OID | OLD29 |
|------------|-------|

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 16:07:14

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 MAR 2021 |
| Time of assessment (00:00-23:59) | 08:26 (24 HR) |
| Vital Signs Date and Time (derived) | 15 MAR 2021 08:26 |
| Temperature (xxx.x) | 97.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 124 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 68 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 16:07:14

Generated On: 09 Jun 2021 16:12:49

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 15 MAR 2021 |
| Time of assessment (00:00-23:59) | 10:06 (24 HR) |
| Vital Signs Date and Time (derived) | 15 MAR 2021 10:06 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 118 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3242264

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 16:07:14

Generated On: 09 Jun 2021 16:12:49

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.

US3242264

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 16:07:14

Generated On: 09 Jun 2021 16:12:49

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 15 MAR 2021

What was the treatment time? (00:00-23:59) 09:33 (24 HR)

Treatment Date and Time (derived) 15 MAR 2021 09:33

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

What was the frequency of the study treatment dosing? ONCE

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

US3242264

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 16:07:14

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 18:15:56

Generated On: 09 Jun 2021 16:12:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3242264

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:15:56

Generated On: 09 Jun 2021 16:12:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242264

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3242264

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

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.

US3242264

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

| | |
|--|------------------------------|
| Was the sample collected? | Yes <input type="checkbox"/> |
| | No <input type="checkbox"/> |
| Collection date (<i>dd MMM yyyy</i>) | <hr/> |
| Collection time (<i>00:00-23:59</i>) | <hr/> |
| Collection date and time (derived) | <hr/> |

US3242264

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | |
|--|--|
| AEID | |
| Adverse event | VIRAL SYNDROME |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 10 OCT 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 17 OCT 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | |
|--|--|
| AEID | |
| Adverse event | BROKEN NOSE |
| 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) | 20 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) | 30 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | |
|--|---|
| 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 | False |
| Concomitant Procedure | True |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

| | |
|--|--|
| AEID | USA-US067-2020-MRNA-1273-P30 1000015 |
| Adverse event | HEAD LACERATION |
| 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) | 20 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) | 30 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 20 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 22 NOV 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

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

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

AT SAFETY PHONE CALL
SUBJECT REPORTED THAT HE
HAD BEEN ATTACKED ON
11/20/2020. HE WAS ADMITTED
TO ER WITH A BROKEN NOSE
AND HEAD LACERATION. HE
WAS DISCHARGED ON
11/22/2020. MEDICAL RECORDS
REQUESTED

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

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

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

Yes ☒

No ☐

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

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------------------------|----------------------------------|
| | 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 2015 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 1990 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 13 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 13 AUG 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication MUPIROCIN 2%

Prophylaxis Yes ☐
No ☒

Indication HEAD LACERATION

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 20 NOV 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication LIDOCAINE OINTMENT 2.5%

Prophylaxis Yes ☐
No ☒

Indication HEAD LACERATION

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 20 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) | 30 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 3 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

Name of Medication JUVEDERM

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 06 Mar 2021 14:45:18

Generated On: 09 Jun 2021 16:12:49

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2019 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) UN UNK 2019 | | |
| 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"/> |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 18:20:53

Generated On: 09 Jun 2021 16:12:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 25 Mar 2021 18:15:56

Generated On: 09 Jun 2021 16:12:49

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 20 NOV 2020 | SUTURES,HEAD | Adverse Event | |
| 24 NOV 2020 | NASAL REDUCTION | Adverse Event | |

US3242264

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:12:49

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:12:49

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 ☐

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

| | |
|--|--|
| SAEID | USA-US067-2020-MRNA-1273-P301000015 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

| | |
|---|--|
| SAEID | USA-US067-2020-MRNA-1273-P301000015 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 25/NOV/2020 12:50 |
| 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 |

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Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 18:20:54

Generated On: 09 Jun 2021 16:12:49

| | |
|---|--|
| SAEID | USA-US067-2020-MRNA-1273-P301000015 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | |
| Investigator's Last Name | |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 06/DEC/2020 12:13 |
| 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

US3242264 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242264

Form: Participant Creation

Generated On: 09 Jun 2021 16:12:49

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:01:47 |
| | | |
| User entered 'US3242264' | RWS_ENDPOINT ENDPOINT (b) (4) | 01 Sep 2020 13:29:52 |
| | | |

US3242264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:18:54 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '01 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 01 Sep 2020 13:29:53 |
| | | |

US3242264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Clinic (Clinic)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:18:54 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'SCRN' | (b) (4), (b) (6) System | 01 Sep 2020 14:18:54 |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered (b) (6) 1971' | RWS_ENDPOINT ENDPOINT (b) (4) | 01 Sep 2020 13:29:54 |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '49' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'YEARS' | (b) (4), (b) (6) System | 01 Sep 2020 14:19:32 |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '49' | (b) (4), (b) (6) System | 01 Sep 2020 14:19:44 |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

Sex

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Male (M)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

White

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'I' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

Unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:12:49

Not reported

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:32 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:44 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'Sep 2020' | (b) (4), (b) (6) System | 01 Sep 2020 14:19:44 |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '2020' | (b) (4), (b) (6) System | 01 Sep 2020 14:19:44 |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Amendment 3 (3)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:44 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:44 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:44 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:44 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:44 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | RWS_ENDPOINT ENDPOINT (b) (4) | 01 Sep 2020 13:29:53 |
| | | |

US3242264

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:12:49

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '1' | (b) (4), (b) (6) System | 01 Sep 2020 14:19:51 |

US3242264

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:51 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:12:49

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:19:58 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

Condition

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| 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) | 01 Sep 2020 14:20:52 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:20:52 |
| | (b) (4) | |
| Data point term sent to Coder | System | 01 Sep 2020 14:20:19 |
| User entered 'Hypertension' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:09 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'UN UNK 2015' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:09 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:09 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:09 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:09 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:09 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'Jan 2015' | (b) (4), (b) (6) System | 01 Sep 2020 14:20:09 |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '2015' | (b) (4), (b) (6) System | 01 Sep 2020 14:20:09 |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:20:09 |

US3242264

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:20:09 |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

Condition

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| 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) | 01 Sep 2020 14:20:51 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:20:51 |
| | (b) (4) | |
| Data point term sent to Coder | System | 01 Sep 2020 14:20:19 |
| User entered 'Hyperlipidemia' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:18 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Un UNK 2017' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:18 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:18 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:18 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:18 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:18 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'Jan 2017' | (b) (4), (b) (6) System | 01 Sep 2020 14:20:18 |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '2017' | (b) (4), (b) (6) System | 01 Sep 2020 14:20:18 |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:20:18 |

US3242264

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:20:18 |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

Condition

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:22:44 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:22:44 |
| | (b) (4) | |
| Data point term sent to Coder | System | 01 Sep 2020 14:21:20 |
| User entered 'Hypothyroidism' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Un UNK 2010' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:20:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'Jan 2010' | (b) (4), (b) (6) System | 01 Sep 2020 14:20:29 |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '2010' | (b) (4), (b) (6) System | 01 Sep 2020 14:20:29 |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:20:29 |

US3242264

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:20:29 |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

Condition

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:23:52 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:23:52 |
| | (b) (4) | |
| Data point term sent to Coder | System | 01 Sep 2020 14:22:23 |
| User entered 'Back Pain' | Donna Toepfer (b) (4) | 01 Sep 2020 14:21:39 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Un UNK 1990' | Donna Toepfer (b) (4) | 01 Sep 2020 14:21:39 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:21:39 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:21:39 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:21:39 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:21:39 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'Jan 1990' | (b) (4), (b) (6) System | 01 Sep 2020 14:21:39 |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '1990' | (b) (4), (b) (6) System | 01 Sep 2020 14:21:39 |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:21:39 |

US3242264

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered empty. | (b) (4), (b) (6) System | 01 Sep 2020 14:21:39 |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

Condition

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:24:41 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 01 Sep 2020 14:24:41 |
| | (b) (4) | |
| Data point term sent to Coder | System | 01 Sep 2020 14:23:25 |
| User entered 'Vasectomy' | Donna Toepfer (b) (4) | 01 Sep 2020 14:22:26 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'UN UNK 1995' | Donna Toepfer (b) (4) | 01 Sep 2020 14:22:26 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:22:26 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:22:26 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'UN UNK 1995' | Donna Toepfer (b) (4) | 01 Sep 2020 14:22:26 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:22:26 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'Jan 1995' | (b) (4), (b) (6) System | 01 Sep 2020 14:22:26 |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '1995' | (b) (4), (b) (6) System | 01 Sep 2020 14:22:26 |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|-------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'Jan 1995' | (b) (4), (b) (6) System | 01 Sep 2020 14:22:26 |

US3242264

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '1995' | (b) (4), (b) (6) System | 01 Sep 2020 14:22:26 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '09:03' | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '1 Sep 2020 09:03' | (b) (4), (b) (6) System | 01 Sep 2020 14:23:29 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '72' in | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| DataPoint set to visible. | System | 01 Sep 2020 14:19:51 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '216' lb | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| DataPoint set to visible. | System | 01 Sep 2020 14:19:51 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered '29.35612' | (b) (4), (b) (6) | |
| | System | 01 Sep 2020 14:23:29 |
| DataPoint set to visible. | System | 01 Sep 2020 14:19:51 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'kg/m2' | (b) (4), (b) (6) | |
| | System | 01 Sep 2020 14:23:29 |
| DataPoint set to visible. | System | 01 Sep 2020 14:19:51 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'bpm' | (b) (4), (b) (6) System | 01 Sep 2020 14:23:29 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 01 Sep 2020 14:23:29 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 01 Sep 2020 14:23:29 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:29 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 01 Sep 2020 14:23:29 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |

US3242264

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |

US3242264

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:38 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 14:23:38 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

[Specify](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'volunteers with homeless-provided meals and softball coach' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

Resides in Nursing Home or Assisted Living Facility

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'l' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| | | |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:12:49

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 08:31:04 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:33 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:42 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:42 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Clinic (Clinic)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:42 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'VISIT1' | System | 01 Sep 2020 14:24:42 |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '01 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 01 Sep 2020 14:10:14 |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '110115' | RWS_ENDPOINT ENDPOINT (b) (4) | 01 Sep 2020 14:10:14 |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT ENDPOINT (b) (4) | 01 Sep 2020 14:10:14 |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:51 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:51 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:51 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:51 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:51 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 23 Sep 2020 18:51:33 |
| | (b) (4) | |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 08:52:43 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 08:52:41 |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

Weight

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Pre-Dose (PREDOSE)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '09:18' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '1 Sep 2020 09:18' | (b) (4), (b) (6) | 01 Sep 2020 15:22:49 |
| | System | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '98.0' F | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Oral (Oral)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '64' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'bpm' | System | 01 Sep 2020 15:22:49 |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '14' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 01 Sep 2020 15:22:49 |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '114' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 01 Sep 2020 15:22:49 |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '70' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 01 Sep 2020 15:22:49 |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered missing code ND - Not Done. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Post-Dose (POSTDOSE)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '10:53' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '1 Sep 2020 10:53' | (b) (4), (b) (6) | 01 Sep 2020 15:22:49 |
| | System | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '98.3' F | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Oral (Oral)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '60' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'bpm' | System | 01 Sep 2020 15:22:49 |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '16' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'breaths/min' | (b) (4), (b) (6) | 01 Sep 2020 15:22:49 |
| | System | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '112' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 01 Sep 2020 15:22:49 |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '70' | Donna Toepfer (b) (4) | 01 Sep 2020 15:22:49 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 01 Sep 2020 15:22:49 |

US3242264

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:57 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:24:57 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:28:06 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:28:06 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:28:06 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'MRNA-1273 OR PLACEBO' | (b) (4), (b) (6) | 01 Sep 2020 14:28:06 |
| | System | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 14:28:06 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '10:23' | Donna Toepfer (b) (4) | 01 Sep 2020 14:28:06 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '1 Sep 2020 10:23' | (b) (4), (b) (6) | 01 Sep 2020 14:28:06 |
| | System | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Left Arm (LEFT ARM)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:28:06 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| DataPoint Verified. | (b) (4), (b) (6) (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| User entered 'ONCE' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'INTRAMUSCULAR' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:30 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:30 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered '10:07' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:30 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '1 Sep 2020 10:07' | (b) (4), (b) (6) | 01 Sep 2020 15:20:30 |
| | System | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:12:49

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '1 Sep 2020' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:45 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:45 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:45 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered '10:03' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:45 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User entered '1 Sep 2020 10:03' | System | 01 Sep 2020 15:20:45 |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:45 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:45 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:08:29 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 15:20:45 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered empty. | (b) (4), (b) (6) | 01 Sep 2020 15:20:45 |
| | System | |

US3242264

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:15:40 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:04 |
| | | |
| | | |

US3242264

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | System | 01 Sep 2020 14:25:04 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:00:11', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '26fbf999-942f-4b1d-bf6b-f7c151798b5e' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 01 Sep 2020 15:00:43 |
| | System | 01 Sep 2020 15:00:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:00:19', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '26fbf999-942f-4b1d-bf6b-f7c151798b5e' User entered '98.3' | (b) (4), (b) (6) System | 01 Sep 2020 15:00:43 |
| | System | 01 Sep 2020 15:00:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:00:23', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '26fbf999-942f-4b1d-bf6b-f7c151798b5e' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Sep 2020 15:00:43 |
| | System | 01 Sep 2020 15:00:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:00:37', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '26fbf999-942f-4b1d-bf6b-f7c151798b5e' User entered '01 Sep 2020 11:00' | (b) (4), (b) (6) System | 01 Sep 2020 15:00:43 |
| | System | 01 Sep 2020 15:00:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 10:43' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 13:13' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:10:15', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'bc00e95a-bef5-4c44-9910-050598e3e38c' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 01 Sep 2020 18:10:43 |
| | System | 01 Sep 2020 18:10:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:10:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'bc00e95a-bef5-4c44-9910-050598e3e38c' User entered '98.4' | (b) (4), (b) (6) System | 01 Sep 2020 18:10:43 |
| | System | 01 Sep 2020 18:10:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:10:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'bc00e95a-bef5-4c44-9910-050598e3e38c' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Sep 2020 18:10:43 |
| | System | 01 Sep 2020 18:10:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:10:36', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'bc00e95a-bef5-4c44-9910-050598e3e38c' User entered '01 Sep 2020 14:10' | (b) (4), (b) (6) System | 01 Sep 2020 18:10:43 |
| | System | 01 Sep 2020 18:10:43 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 14:08' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 2' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:03:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'cab3c451-3807-4c25-8c7c-75f50392befe' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:23 |
| | System | 02 Sep 2020 16:04:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:03:40', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'cab3c451-3807-4c25-8c7c-75f50392befe' User entered '98.4' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:23 |
| | System | 02 Sep 2020 16:04:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:03:46', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'cab3c451-3807-4c25-8c7c-75f50392befe' User entered 'No (N)' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:23 |
| | System | 02 Sep 2020 16:04:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:03:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'cab3c451-3807-4c25-8c7c-75f50392befe' User entered '02 Sep 2020 12:03' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:23 |
| | System | 02 Sep 2020 16:04:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 3' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:20', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '905b8bdc-674c-46da-87f2-3ebbc4a6ed93' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 03 Sep 2020 16:05:55 |
| | System | 03 Sep 2020 16:05:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '905b8bdc-674c-46da-87f2-3ebbc4a6ed93' User entered '99.0' | (b) (4), (b) (6) System | 03 Sep 2020 16:05:55 |
| | System | 03 Sep 2020 16:05:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '905b8bdc-674c-46da-87f2-3ebbc4a6ed93' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 03 Sep 2020 16:05:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:40', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '905b8bdc-674c-46da-87f2-3ebbc4a6ed93' User entered '03 Sep 2020 12:03' | (b) (4), (b) (6) System | 03 Sep 2020 16:05:55 |
| | System | 03 Sep 2020 16:05:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 4' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:35:43', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4b02fc51-4cc2-4d54-9135-7d22f72e63fd' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:07 |
| | System | 05 Sep 2020 13:36:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:35:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4b02fc51-4cc2-4d54-9135-7d22f72e63fd' User entered '98.5' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:07 |
| | System | 05 Sep 2020 13:36:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:35:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4b02fc51-4cc2-4d54-9135-7d22f72e63fd' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:07 |
| | System | 05 Sep 2020 13:36:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:02', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4b02fc51-4cc2-4d54-9135-7d22f72e63fd' User entered '05 Sep 2020 09:36' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:07 |
| | System | 05 Sep 2020 13:36:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 5' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:14', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd0bb4b21-bab4-4b2b-b465-e10538c50381' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:36 |
| | System | 05 Sep 2020 17:07:36 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:26', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd0bb4b21-bab4-4b2b-b465-e10538c50381' User entered '98.3' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:36 |
| | System | 05 Sep 2020 17:07:36 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd0bb4b21-bab4-4b2b-b465-e10538c50381' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:36 |
| | System | 05 Sep 2020 17:07:36 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:33', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd0bb4b21-bab4-4b2b-b465-e10538c50381' User entered '05 Sep 2020 13:07' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:36 |
| | System | 05 Sep 2020 17:07:36 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '06 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 6' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:20:10', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dc782853-c457-405a-9dbe-1b9de1df593c' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 07 Sep 2020 13:20:54 |
| | System | 07 Sep 2020 13:20:54 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:20:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dc782853-c457-405a-9dbe-1b9de1df593c' User entered '99.0' | (b) (4), (b) (6) System | 07 Sep 2020 13:20:54 |
| | System | 07 Sep 2020 13:20:54 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:20:46', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dc782853-c457-405a-9dbe-1b9de1df593c' User entered 'No (N)' | (b) (4), (b) (6) System | 07 Sep 2020 13:20:54 |
| | System | 07 Sep 2020 13:20:54 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:20:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dc782853-c457-405a-9dbe-1b9de1df593c' User entered '07 Sep 2020 09:20' | (b) (4), (b) (6) System | 07 Sep 2020 13:20:54 |
| | System | 07 Sep 2020 13:20:54 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '06 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '07 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 7' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:57:39', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '30c3a1f6-8fed-4299-99c7-d200b7d88a69' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 08 Sep 2020 13:57:57 |
| | System | 08 Sep 2020 13:57:57 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:57:46', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '30c3a1f6-8fed-4299-99c7-d200b7d88a69' User entered '98.5' | (b) (4), (b) (6) System | 08 Sep 2020 13:57:57 |
| | System | 08 Sep 2020 13:57:57 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:57:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '30c3a1f6-8fed-4299-99c7-d200b7d88a69' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 08 Sep 2020 13:57:57 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:57:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '30c3a1f6-8fed-4299-99c7-d200b7d88a69' User entered '08 Sep 2020 09:57' | (b) (4), (b) (6) System | 08 Sep 2020 13:57:57 |
| | System | 08 Sep 2020 13:57:57 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '07 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '08 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:00:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dee34077-8c84-4c23-abe5-9870e4ddc9af' User entered 'None (1)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:23 |
| | System | 01 Sep 2020 15:01:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:08', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dee34077-8c84-4c23-abe5-9870e4ddc9af' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:23 |
| | System | 01 Sep 2020 15:01:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:12', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dee34077-8c84-4c23-abe5-9870e4ddc9af' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:23 |
| | System | 01 Sep 2020 15:01:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:16', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dee34077-8c84-4c23-abe5-9870e4ddc9af' User entered 'None (1)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:23 |
| | System | 01 Sep 2020 15:01:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:20', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dee34077-8c84-4c23-abe5-9870e4ddc9af' User entered '01 Sep 2020 11:01' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:23 |
| | System | 01 Sep 2020 15:01:23 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 10:43' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 13:13' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:11:09', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9d75d283-fbbd-4076-89e7-0e5102b579d2' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 01 Sep 2020 18:12:00 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:11:27', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9d75d283-fbbd-4076-89e7-0e5102b579d2' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:00 |
| | System | 01 Sep 2020 18:12:00 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:11:45', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9d75d283-fbbd-4076-89e7-0e5102b579d2' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 01 Sep 2020 18:12:00 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:11:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9d75d283-fbbd-4076-89e7-0e5102b579d2' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 01 Sep 2020 18:12:00 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:11:58', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9d75d283-fbbd-4076-89e7-0e5102b579d2' | (b) (4), (b) (6) | |
| | System | 01 Sep 2020 18:12:00 |
| User entered '01 Sep 2020 14:11' | System | 01 Sep 2020 18:12:00 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 14:08' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 2' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:03:58', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4488b0a5-e66a-4c21-802c-0d3e60aa56cf' User entered 'None (1)' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:48 |
| | System | 02 Sep 2020 16:04:48 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:03', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4488b0a5-e66a-4c21-802c-0d3e60aa56cf' User entered 'No (N)' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:48 |
| | System | 02 Sep 2020 16:04:48 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:08', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4488b0a5-e66a-4c21-802c-0d3e60aa56cf' User entered 'No (N)' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:48 |
| | System | 02 Sep 2020 16:04:48 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:14', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4488b0a5-e66a-4c21-802c-0d3e60aa56cf' User entered 'None (1)' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:48 |
| | System | 02 Sep 2020 16:04:48 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:20', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4488b0a5-e66a-4c21-802c-0d3e60aa56cf' User entered '02 Sep 2020 12:04' | (b) (4), (b) (6) System | 02 Sep 2020 16:04:48 |
| | System | 02 Sep 2020 16:04:48 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 3' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:45', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6725076c-f267-4ef6-95de-6a23bf214d80' User entered 'None (1)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:12 |
| | System | 03 Sep 2020 16:06:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6725076c-f267-4ef6-95de-6a23bf214d80' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:12 |
| | System | 03 Sep 2020 16:06:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6725076c-f267-4ef6-95de-6a23bf214d80' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:12 |
| | System | 03 Sep 2020 16:06:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6725076c-f267-4ef6-95de-6a23bf214d80' User entered 'None (1)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:12 |
| | System | 03 Sep 2020 16:06:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:03:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6725076c-f267-4ef6-95de-6a23bf214d80' User entered '03 Sep 2020 12:03' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:12 |
| | System | 03 Sep 2020 16:06:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 4' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:06', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6b2272bf-54d0-4046-93b6-785efc1e3cc3' User entered 'None (1)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:20 |
| | System | 05 Sep 2020 13:36:20 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:10', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6b2272bf-54d0-4046-93b6-785efc1e3cc3' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:20 |
| | System | 05 Sep 2020 13:36:20 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:12', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6b2272bf-54d0-4046-93b6-785efc1e3cc3' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:20 |
| | System | 05 Sep 2020 13:36:20 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:15', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6b2272bf-54d0-4046-93b6-785efc1e3cc3' User entered 'None (1)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:20 |
| | System | 05 Sep 2020 13:36:20 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:17', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6b2272bf-54d0-4046-93b6-785efc1e3cc3' User entered '05 Sep 2020 09:36' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:20 |
| | System | 05 Sep 2020 13:36:20 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 5' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:37', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6ec70a9b-f989-4c09-b70c-0781bfdbe107' User entered 'None (1)' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:55 |
| | System | 05 Sep 2020 17:07:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:42', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6ec70a9b-f989-4c09-b70c-0781bfdbe107' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:55 |
| | System | 05 Sep 2020 17:07:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:45', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6ec70a9b-f989-4c09-b70c-0781bfdbe107' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:55 |
| | System | 05 Sep 2020 17:07:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6ec70a9b-f989-4c09-b70c-0781bfdbe107' User entered 'None (1)' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:55 |
| | System | 05 Sep 2020 17:07:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:50', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '6ec70a9b-f989-4c09-b70c-0781bfdbe107' User entered '05 Sep 2020 13:07' | (b) (4), (b) (6) System | 05 Sep 2020 17:07:55 |
| | System | 05 Sep 2020 17:07:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '06 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 6' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:20:57', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3fdab26e-846f-489e-a0ae-65dd6b03c1d4' | (b) (4), (b) (6) | |
| | System | 07 Sep 2020 13:21:15 |
| User entered 'None (1)' | System | 07 Sep 2020 13:21:15 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:02', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3fdab26e-846f-489e-a0ae-65dd6b03c1d4' User entered 'No (N)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:15 |
| | System | 07 Sep 2020 13:21:15 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:04', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3fdab26e-846f-489e-a0ae-65dd6b03c1d4' User entered 'No (N)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:15 |
| | System | 07 Sep 2020 13:21:15 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:08', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3fdab26e-846f-489e-a0ae-65dd6b03c1d4' User entered 'None (1)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:15 |
| | System | 07 Sep 2020 13:21:15 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:13', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3fdab26e-846f-489e-a0ae-65dd6b03c1d4' User entered '07 Sep 2020 09:21' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:15 |
| | System | 07 Sep 2020 13:21:15 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '06 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '07 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 7' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:01', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '10b3d6a3-2731-49ad-a4db-c7a733ee8375' User entered 'None (1)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:21 |
| | System | 08 Sep 2020 13:58:21 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:05', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '10b3d6a3-2731-49ad-a4db-c7a733ee8375' User entered 'No (N)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:21 |
| | System | 08 Sep 2020 13:58:21 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:11', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '10b3d6a3-2731-49ad-a4db-c7a733ee8375' User entered 'No (N)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:21 |
| | System | 08 Sep 2020 13:58:21 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:14', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '10b3d6a3-2731-49ad-a4db-c7a733ee8375' User entered 'None (1)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:21 |
| | System | 08 Sep 2020 13:58:21 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:20', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '10b3d6a3-2731-49ad-a4db-c7a733ee8375' User entered '08 Sep 2020 09:58' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:21 |
| | System | 08 Sep 2020 13:58:21 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '07 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '08 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:32', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:35', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:40', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:43', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T11:01:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3d636529-617b-49e6-b74f-4169c67c367f' User entered '01 Sep 2020 11:01' | (b) (4), (b) (6) System | 01 Sep 2020 15:01:55 |
| | System | 01 Sep 2020 15:01:55 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 10:43' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 13:13' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 1, after vaccination (at home)' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:17', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:21', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:26', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:31', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-01T14:12:47', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1cdb41b4-7d5c-4ae4-b3e0-1e902d54027b' User entered '01 Sep 2020 14:12' | (b) (4), (b) (6) System | 01 Sep 2020 18:12:50 |
| | System | 01 Sep 2020 18:12:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Sep 2020 14:08' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 2' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:33', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:36', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:40', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:42', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered 'No (N)' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-02T12:04:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '55bf56ed-69a5-42b3-b6d8-c545f6db51cf' User entered '02 Sep 2020 12:04' | (b) (4), (b) (6) System | 02 Sep 2020 16:05:07 |
| | System | 02 Sep 2020 16:05:07 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 3' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:05', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:50 |
| | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:21', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:50 |
| | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:25', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:50 |
| | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:27', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:50 |
| | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:39', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' | (b) (4), (b) (6) | |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)' | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:50 |
| | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:47', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:50 |
| | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-03T12:04:49', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a53d7b17-0eb7-4c7f-8f81-22d36dd0c2e7' User entered '03 Sep 2020 12:04' | (b) (4), (b) (6) System | 03 Sep 2020 16:06:50 |
| | System | 03 Sep 2020 16:06:50 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 4' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:23', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:45', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T09:36:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '21d400fd-7a39-413b-9bfc-4220f1ba6fae' User entered '05 Sep 2020 09:36' | (b) (4), (b) (6) System | 05 Sep 2020 13:36:59 |
| | System | 05 Sep 2020 13:36:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 5' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:07:58', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:08:01', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:08:03', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:08:05', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:08:08', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-05T13:08:09', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '668afcd6-7df2-4009-966c-e716583c4628' User entered '05 Sep 2020 13:08' | (b) (4), (b) (6) System | 05 Sep 2020 17:08:12 |
| | System | 05 Sep 2020 17:08:12 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '06 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 6' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:19', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered 'None (0)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered 'None (0)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered 'None (0)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:32', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered 'None (0)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered 'None (0)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:37', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered 'None (0)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered 'No (N)' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-07T09:21:49', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '96b2563d-00f7-42bc-86eb-7f7b1bed77e7' User entered '07 Sep 2020 09:21' | (b) (4), (b) (6) System | 07 Sep 2020 13:21:52 |
| | System | 07 Sep 2020 13:21:52 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '06 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '07 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 7' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:52', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered 'None (0)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered 'None (0)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:31', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered 'None (0)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:35', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered 'None (0)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:40', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered 'None (0)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:44', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered 'None (0)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered 'No (N)' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-08T09:58:55', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7a4e1677-f3f9-49c7-b4d2-28ded1973c26' User entered '08 Sep 2020 09:58' | (b) (4), (b) (6) System | 08 Sep 2020 13:58:59 |
| | System | 08 Sep 2020 13:58:59 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '07 Sep 2020 12:00' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '08 Sep 2020 11:59' | (b) (4), (b) (6) System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | Grace Newville (b) (4) | 11 Sep 2020 14:18:34 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '11 Sep 2020' | Grace Newville (b) (4) | 11 Sep 2020 14:18:34 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Grace Newville (b) (4) | 11 Sep 2020 14:18:34 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered empty. | Grace Newville (b) (4) | 11 Sep 2020 14:18:34 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | Grace Newville (b) (4) | 11 Sep 2020 14:18:40 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | System | 11 Sep 2020 14:18:40 |

US3242264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | Grace Newville (b) (4) | 17 Sep 2020 22:34:53 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '17 Sep 2020' | Grace Newville (b) (4) | 17 Sep 2020 22:34:53 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Grace Newville (b) (4) | 17 Sep 2020 22:34:53 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered empty. | Grace Newville (b) (4) | 17 Sep 2020 22:34:53 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | Grace Newville (b) (4) | 17 Sep 2020 22:35:06 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | (b) (4), (b) (6) System | 17 Sep 2020 22:35:06 |

US3242264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 18:37:50 |
| | | |

US3242264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '24 Sep 2020' | (b) (4), (b) (6) | 24 Sep 2020 18:37:50 |
| | | |

US3242264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 24 Sep 2020 18:37:50 |
| | | |

US3242264

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered empty. | (b) (4), (b) (6) | 24 Sep 2020 18:37:50 |
| | | |

US3242264

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 24 Sep 2020 18:37:53 |
| | | |

US3242264

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | System | 24 Sep 2020 18:37:53 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:22 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '28 Sep 2020' | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:22 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Clinic (Clinic)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:22 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'VISIT2' | System | 28 Sep 2020 15:27:22 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Pre-Dose (PREDOSE)' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '28 Sep 2020' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '10:51' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '28 Sep 2020 10:51' | (b) (4), (b) (6) | 28 Sep 2020 17:23:52 |
| | System | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '97.9' F | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Oral (Oral)' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '76' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'bpm' | System | 28 Sep 2020 17:23:52 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '16' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 28 Sep 2020 17:23:52 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '116' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) | 28 Sep 2020 17:23:52 |
| | System | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '70' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) | 28 Sep 2020 17:23:52 |
| | System | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Post-Dose (POSTDOSE)' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '28 Sep 2020' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '12:08' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '28 Sep 2020 12:08' | (b) (4), (b) (6) | |
| | System | 28 Sep 2020 17:23:52 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '98.5' F | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Oral (Oral)' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '72' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'bpm' | (b) (4), (b) (6) System | 28 Sep 2020 17:23:52 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '16' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 28 Sep 2020 17:23:52 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '112' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 28 Sep 2020 17:23:52 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '72' | Erynn McKinley (b) (4) | 28 Sep 2020 17:23:52 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 28 Sep 2020 17:23:52 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:32 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:32 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:45:48 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 28 Sep 2020 15:45:48 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 28 Sep 2020 15:45:48 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'MRNA-1273 OR PLACEBO' | (b) (4), (b) (6) | 28 Sep 2020 15:45:48 |
| | System | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '28 Sep 2020' | Erynn McKinley (b) (4) | 28 Sep 2020 15:45:48 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '11:43' | Erynn McKinley (b) (4) | 28 Sep 2020 15:45:48 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '28 Sep 2020 11:43' | (b) (4), (b) (6) | 28 Sep 2020 15:45:48 |
| | System | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Left Arm (LEFT ARM)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:45:48 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'ONCE' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'INTRAMUSCULAR' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:56 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '28 Sep 2020' | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:56 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '11:43' reason for change: Data Entry Error | Erynn McKinley (b) (4) | 28 Sep 2020 15:46:10 |
| | (b) (4) | |
| User entered '11:13' | Erynn McKinley (b) (4) | 28 Sep 2020 15:27:56 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User entered '28 Sep 2020 11:43' | System | 28 Sep 2020 15:46:10 |
| User entered '28 Sep 2020 11:13' | System | 28 Sep 2020 15:27:56 |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:12:49

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '28 Sep 2020' | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:26 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:26 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:26 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '11:05' | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:26 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '28 Sep 2020 11:05' | (b) (4), (b) (6) | 28 Sep 2020 15:28:26 |
| | System | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:26 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:26 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:26 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered empty. | (b) (4), (b) (6) | 28 Sep 2020 15:28:26 |
| | System | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 28 Sep 2020 15:28:37 |
| | (b) (4) | |

US3242264

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '1' | (b) (4), (b) (6) | 28 Sep 2020 15:28:37 |
| | System | |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:13:43', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0c2265dd-474f-436d-add0-fe68574cac17' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:02 |
| | System | 28 Sep 2020 16:14:02 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:13:50', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0c2265dd-474f-436d-add0-fe68574cac17' User entered '98.5' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:02 |
| | System | 28 Sep 2020 16:14:02 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:13:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0c2265dd-474f-436d-add0-fe68574cac17' User entered 'No (N)' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:02 |
| | System | 28 Sep 2020 16:14:02 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:13:58', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0c2265dd-474f-436d-add0-fe68574cac17' User entered '28 Sep 2020 12:13' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:02 |
| | System | 28 Sep 2020 16:14:02 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '28 Sep 2020 12:03' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '28 Sep 2020 14:33' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:29:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3b2aa784-cc64-4839-bd78-944c88988ce1' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 29 Sep 2020 10:30:12 |
| | System | 29 Sep 2020 10:30:12 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:02', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3b2aa784-cc64-4839-bd78-944c88988ce1' User entered '98.5' | (b) (4), (b) (6) System | 29 Sep 2020 10:30:12 |
| | System | 29 Sep 2020 10:30:12 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:05', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3b2aa784-cc64-4839-bd78-944c88988ce1' User entered 'No (N)' | (b) (4), (b) (6) System | 29 Sep 2020 10:30:12 |
| | System | 29 Sep 2020 10:30:12 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:10', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3b2aa784-cc64-4839-bd78-944c88988ce1' User entered '29 Sep 2020 06:30' | (b) (4), (b) (6) System | 29 Sep 2020 10:30:12 |
| | System | 29 Sep 2020 10:30:12 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '28 Sep 2020 15:28' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '29 Sep 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 2' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '5b5a41f2-ba9b-4055-8682-1fd6b35b7c20' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 29 Sep 2020 19:11:58 |
| | System | 29 Sep 2020 19:11:58 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:36', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '5b5a41f2-ba9b-4055-8682-1fd6b35b7c20' User entered '98.9' | (b) (4), (b) (6) System | 29 Sep 2020 19:11:58 |
| | System | 29 Sep 2020 19:11:58 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:39', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '5b5a41f2-ba9b-4055-8682-1fd6b35b7c20' User entered 'No (N)' | (b) (4), (b) (6) System | 29 Sep 2020 19:11:58 |
| | System | 29 Sep 2020 19:11:58 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:44', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '5b5a41f2-ba9b-4055-8682-1fd6b35b7c20' User entered '29 Sep 2020 15:11' | (b) (4), (b) (6) System | 29 Sep 2020 19:11:58 |
| | System | 29 Sep 2020 19:11:58 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '29 Sep 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '30 Sep 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 3' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:20', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '69061340-268f-4bf5-a06b-9264ea3223f9' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 30 Sep 2020 18:35:37 |
| | System | 30 Sep 2020 18:35:37 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:26', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '69061340-268f-4bf5-a06b-9264ea3223f9' User entered '99.1' | (b) (4), (b) (6) System | 30 Sep 2020 18:35:37 |
| | System | 30 Sep 2020 18:35:37 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '69061340-268f-4bf5-a06b-9264ea3223f9' User entered 'No (N)' | (b) (4), (b) (6) System | 30 Sep 2020 18:35:37 |
| | System | 30 Sep 2020 18:35:37 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '69061340-268f-4bf5-a06b-9264ea3223f9' User entered '30 Sep 2020 14:35' | (b) (4), (b) (6) System | 30 Sep 2020 18:35:37 |
| | System | 30 Sep 2020 18:35:37 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '30 Sep 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '01 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 4' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:15', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3905c74c-b361-4745-ad89-fc9230b4f1ed' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:31 |
| | System | 01 Oct 2020 16:52:31 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:21', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3905c74c-b361-4745-ad89-fc9230b4f1ed' User entered '98.5' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:31 |
| | System | 01 Oct 2020 16:52:31 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:23', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3905c74c-b361-4745-ad89-fc9230b4f1ed' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:31 |
| | System | 01 Oct 2020 16:52:31 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3905c74c-b361-4745-ad89-fc9230b4f1ed' User entered '01 Oct 2020 12:52' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:31 |
| | System | 01 Oct 2020 16:52:31 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '01 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '02 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 5' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4ce47e8d-ed6a-429c-baae-a750eede0498' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 02 Oct 2020 17:09:45 |
| | System | 02 Oct 2020 17:09:45 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:35', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4ce47e8d-ed6a-429c-baae-a750eede0498' User entered '98.7' | (b) (4), (b) (6) System | 02 Oct 2020 17:09:45 |
| | System | 02 Oct 2020 17:09:45 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4ce47e8d-ed6a-429c-baae-a750eede0498' User entered 'No (N)' | (b) (4), (b) (6) System | 02 Oct 2020 17:09:45 |
| | System | 02 Oct 2020 17:09:45 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '4ce47e8d-ed6a-429c-baae-a750eede0498' User entered '02 Oct 2020 13:09' | (b) (4), (b) (6) System | 02 Oct 2020 17:09:45 |
| | System | 02 Oct 2020 17:09:45 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '02 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '03 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 6' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:19', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b738642c-a8e4-440a-9d7d-33e177f6b041' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:00 |
| | System | 03 Oct 2020 16:02:00 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:27', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b738642c-a8e4-440a-9d7d-33e177f6b041' User entered '99.1' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:00 |
| | System | 03 Oct 2020 16:02:00 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:33', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b738642c-a8e4-440a-9d7d-33e177f6b041' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:00 |
| | System | 03 Oct 2020 16:02:00 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:35', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b738642c-a8e4-440a-9d7d-33e177f6b041' User entered '03 Oct 2020 12:01' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:00 |
| | System | 03 Oct 2020 16:02:00 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '03 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '04 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 7' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:54:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '57bc7e29-527c-4a19-882b-8fd7cf50d27f' User entered 'Yes (Y)' | (b) (4), (b) (6) System | 05 Oct 2020 12:54:56 |
| | System | 05 Oct 2020 12:54:56 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:54:44', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '57bc7e29-527c-4a19-882b-8fd7cf50d27f' User entered '98.3' | (b) (4), (b) (6) System | 05 Oct 2020 12:54:56 |
| | System | 05 Oct 2020 12:54:56 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:54:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '57bc7e29-527c-4a19-882b-8fd7cf50d27f' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Oct 2020 12:54:56 |
| | System | 05 Oct 2020 12:54:56 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:54:50', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '57bc7e29-527c-4a19-882b-8fd7cf50d27f' User entered '05 Oct 2020 08:54' | (b) (4), (b) (6) System | 05 Oct 2020 12:54:56 |
| | System | 05 Oct 2020 12:54:56 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '04 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| User entered '05 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:03', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd6e4ccc6-46b7-4f03-9720-07ac76612dc9' User entered 'None (1)' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:29 |
| | System | 28 Sep 2020 16:14:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:11', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd6e4ccc6-46b7-4f03-9720-07ac76612dc9' User entered 'No (N)' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:29 |
| | System | 28 Sep 2020 16:14:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:18', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd6e4ccc6-46b7-4f03-9720-07ac76612dc9' User entered 'No (N)' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:29 |
| | System | 28 Sep 2020 16:14:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:22', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd6e4ccc6-46b7-4f03-9720-07ac76612dc9' User entered 'None (1)' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:29 |
| | System | 28 Sep 2020 16:14:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'd6e4ccc6-46b7-4f03-9720-07ac76612dc9' User entered '28 Sep 2020 12:14' | (b) (4), (b) (6) System | 28 Sep 2020 16:14:29 |
| | System | 28 Sep 2020 16:14:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '28 Sep 2020 12:03' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '28 Sep 2020 14:33' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:15', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef89f4e9-4b9f-4337-ba02-771f493d5298' | (b) (4), (b) (6) | |
| | System | 29 Sep 2020 10:30:35 |
| User entered 'None (1)' | System | 29 Sep 2020 10:30:35 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:20', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef89f4e9-4b9f-4337-ba02-771f493d5298' | (b) (4), (b) (6) | |
| | System | 29 Sep 2020 10:30:35 |
| User entered 'No (N)' | System | 29 Sep 2020 10:30:35 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:25', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef89f4e9-4b9f-4337-ba02-771f493d5298' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 29 Sep 2020 10:30:35 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef89f4e9-4b9f-4337-ba02-771f493d5298' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 29 Sep 2020 10:30:35 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:33', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef89f4e9-4b9f-4337-ba02-771f493d5298' User entered '29 Sep 2020 06:30' | (b) (4), (b) (6) System | 29 Sep 2020 10:30:35 |
| | System | 29 Sep 2020 10:30:35 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '28 Sep 2020 15:28' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '29 Sep 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 2' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:47', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '94b36240-7513-4cc0-b1ac-0627bf8de9ae' User entered 'None (1)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:08 |
| | System | 29 Sep 2020 19:12:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '94b36240-7513-4cc0-b1ac-0627bf8de9ae' User entered 'No (N)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:08 |
| | System | 29 Sep 2020 19:12:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '94b36240-7513-4cc0-b1ac-0627bf8de9ae' User entered 'No (N)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:08 |
| | System | 29 Sep 2020 19:12:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '94b36240-7513-4cc0-b1ac-0627bf8de9ae' User entered 'None (1)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:08 |
| | System | 29 Sep 2020 19:12:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:11:59', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '94b36240-7513-4cc0-b1ac-0627bf8de9ae' User entered '29 Sep 2020 15:11' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:08 |
| | System | 29 Sep 2020 19:12:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '29 Sep 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '30 Sep 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 3' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '80887b13-c55e-480b-b125-ee7b832768a2' | (b) (4), (b) (6) | |
| | System | 30 Sep 2020 18:35:57 |
| User entered 'None (1)' | System | 30 Sep 2020 18:35:57 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '80887b13-c55e-480b-b125-ee7b832768a2' User entered 'No (N)' | (b) (4), (b) (6) System | 30 Sep 2020 18:35:57 |
| | System | 30 Sep 2020 18:35:57 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '80887b13-c55e-480b-b125-ee7b832768a2' User entered 'No (N)' | (b) (4), (b) (6) System | 30 Sep 2020 18:35:57 |
| | System | 30 Sep 2020 18:35:57 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '80887b13-c55e-480b-b125-ee7b832768a2' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 30 Sep 2020 18:35:57 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:35:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '80887b13-c55e-480b-b125-ee7b832768a2' User entered '30 Sep 2020 14:35' | (b) (4), (b) (6) System | 30 Sep 2020 18:35:57 |
| | System | 30 Sep 2020 18:35:57 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '30 Sep 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 4' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:32', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8ecfe7a2-dc29-471a-aa20-543b27a4275f' User entered 'None (1)' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:43 |
| | System | 01 Oct 2020 16:52:43 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8ecfe7a2-dc29-471a-aa20-543b27a4275f' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:43 |
| | System | 01 Oct 2020 16:52:43 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:36', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8ecfe7a2-dc29-471a-aa20-543b27a4275f' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:43 |
| | System | 01 Oct 2020 16:52:43 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8ecfe7a2-dc29-471a-aa20-543b27a4275f' User entered 'None (1)' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:43 |
| | System | 01 Oct 2020 16:52:43 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8ecfe7a2-dc29-471a-aa20-543b27a4275f' User entered '01 Oct 2020 12:52' | (b) (4), (b) (6) System | 01 Oct 2020 16:52:43 |
| | System | 01 Oct 2020 16:52:43 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 5' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:45', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '37ce1d3a-bb23-49af-9e9a-9f99fc6b3fff' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 02 Oct 2020 17:10:06 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:49', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '37ce1d3a-bb23-49af-9e9a-9f99fc6b3fff' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 02 Oct 2020 17:10:06 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:52', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '37ce1d3a-bb23-49af-9e9a-9f99fc6b3fff' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 02 Oct 2020 17:10:06 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:09:55', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '37ce1d3a-bb23-49af-9e9a-9f99fc6b3fff' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 02 Oct 2020 17:10:06 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:03', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '37ce1d3a-bb23-49af-9e9a-9f99fc6b3fff' User entered '02 Oct 2020 13:10' | (b) (4), (b) (6) System | 02 Oct 2020 17:10:06 |
| | System | 02 Oct 2020 17:10:06 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 6' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e069d082-822d-439e-9fff-2c14391a055a' User entered 'None (1)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:15 |
| | System | 03 Oct 2020 16:02:15 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:39', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e069d082-822d-439e-9fff-2c14391a055a' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:15 |
| | System | 03 Oct 2020 16:02:15 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e069d082-822d-439e-9fff-2c14391a055a' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:15 |
| | System | 03 Oct 2020 16:02:15 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:43', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e069d082-822d-439e-9fff-2c14391a055a' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 03 Oct 2020 16:02:15 |
| | System | 03 Oct 2020 16:02:15 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:44', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e069d082-822d-439e-9fff-2c14391a055a' User entered '03 Oct 2020 12:01' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:15 |
| | System | 03 Oct 2020 16:02:15 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 7' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:54:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '66691cf6-73e9-46ed-9699-80322a80ae56' User entered 'None (1)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:07 |
| | System | 05 Oct 2020 12:55:07 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:54:57', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '66691cf6-73e9-46ed-9699-80322a80ae56' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:07 |
| | System | 05 Oct 2020 12:55:07 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:54:59', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '66691cf6-73e9-46ed-9699-80322a80ae56' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:07 |
| | System | 05 Oct 2020 12:55:07 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:01', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '66691cf6-73e9-46ed-9699-80322a80ae56' | (b) (4), (b) (6) | |
| User entered 'None (1)' | System | 05 Oct 2020 12:55:07 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:04', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '66691cf6-73e9-46ed-9699-80322a80ae56' User entered '05 Oct 2020 08:55' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:07 |
| | System | 05 Oct 2020 12:55:07 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered 'None (0)' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:33', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered 'None (0)' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:36', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered 'None (0)' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:39', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered 'None (0)' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered 'None (0)' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:14:44', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered 'None (0)' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:15:03', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered 'No (N)' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-28T12:15:06', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3c255543-54d9-4c81-98a3-1f7da4d33efb' User entered '28 Sep 2020 12:15' | (b) (4), (b) (6) System | 28 Sep 2020 16:15:08 |
| | System | 28 Sep 2020 16:15:08 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '28 Sep 2020 12:03' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '28 Sep 2020 14:33' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 1, after vaccination (at home)' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:46', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' | (b) (4), (b) (6) | |
| | System | 29 Sep 2020 10:31:32 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:50', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 10:31:32 |
| | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 10:31:32 |
| | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:30:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 10:31:32 |
| | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:31:03', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 10:31:32 |
| | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:31:06', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 10:31:32 |
| | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:31:11', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' User entered 'No (N)' | (b) (4), (b) (6) System | 29 Sep 2020 10:31:32 |
| | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T06:31:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a092658e-985d-4dac-9e2f-2121ba6f57a8' User entered '29 Sep 2020 06:31' | (b) (4), (b) (6) System | 29 Sep 2020 10:31:32 |
| | System | 29 Sep 2020 10:31:32 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '28 Sep 2020 15:28' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '29 Sep 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 2' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:04', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:07', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:09', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:13', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:15', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:17', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered 'None (0)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:22', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered 'No (N)' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-29T15:12:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fbb0d897-bf5e-476d-a78a-6d19827d6e78' User entered '29 Sep 2020 15:12' | (b) (4), (b) (6) System | 29 Sep 2020 19:12:26 |
| | System | 29 Sep 2020 19:12:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '29 Sep 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '30 Sep 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 3' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:36:15', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' | (b) (4), (b) (6) | |
| User entered 'No interference with activity (1)' | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:37:14', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' | (b) (4), (b) (6) | |
| User entered 'Some interference with activity (2)' | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:36:31', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' User entered 'None (0)' | (b) (4), (b) (6) System | 30 Sep 2020 18:37:26 |
| | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:36:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' User entered 'None (0)' | (b) (4), (b) (6) System | 30 Sep 2020 18:37:26 |
| | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:36:43', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' User entered 'None (0)' | (b) (4), (b) (6) System | 30 Sep 2020 18:37:26 |
| | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:36:46', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' User entered 'None (0)' | (b) (4), (b) (6) System | 30 Sep 2020 18:37:26 |
| | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:36:49', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' User entered 'No (N)' | (b) (4), (b) (6) System | 30 Sep 2020 18:37:26 |
| | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-09-30T14:37:23', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f75fada4-61ad-4180-9f07-e5c7a46bec76' User entered '30 Sep 2020 14:37' | (b) (4), (b) (6) System | 30 Sep 2020 18:37:26 |
| | System | 30 Sep 2020 18:37:26 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '30 Sep 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 4' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:49', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' | (b) (4), (b) (6) | |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:52:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' | (b) (4), (b) (6) | |
| | System | 01 Oct 2020 16:53:33 |
| User entered 'No interference with activity (1)' | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:53:05', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' | (b) (4), (b) (6) | |
| | System | 01 Oct 2020 16:53:33 |
| User entered 'No interference with activity (1)' | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:53:08', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Oct 2020 16:53:33 |
| | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:53:11', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Oct 2020 16:53:33 |
| | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:53:13', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' User entered 'None (0)' | (b) (4), (b) (6) System | 01 Oct 2020 16:53:33 |
| | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:53:16', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' User entered 'No (N)' | (b) (4), (b) (6) System | 01 Oct 2020 16:53:33 |
| | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-01T12:53:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '75576b0e-8440-404b-bec3-d917431caa07' User entered '01 Oct 2020 12:53' | (b) (4), (b) (6) System | 01 Oct 2020 16:53:33 |
| | System | 01 Oct 2020 16:53:33 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '01 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 5' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:13', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' | (b) (4), (b) (6) | |
| | System | 02 Oct 2020 17:10:38 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:16', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' | (b) (4), (b) (6) | |
| | System | 02 Oct 2020 17:10:38 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:19', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Oct 2020 17:10:38 |
| | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:22', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Oct 2020 17:10:38 |
| | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Oct 2020 17:10:38 |
| | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:27', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' User entered 'None (0)' | (b) (4), (b) (6) System | 02 Oct 2020 17:10:38 |
| | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' User entered 'No (N)' | (b) (4), (b) (6) System | 02 Oct 2020 17:10:38 |
| | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-02T13:10:32', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b9f27614-f369-4314-b456-4b0c2cf4a42e' User entered '02 Oct 2020 13:10' | (b) (4), (b) (6) System | 02 Oct 2020 17:10:38 |
| | System | 02 Oct 2020 17:10:38 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '02 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 6' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:50', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:52', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:54', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:55', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:57', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered 'None (0)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:01:59', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered 'No (N)' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-03T12:02:01', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '9739cd1e-b87b-4f87-a734-ccb2fc860f00' User entered '03 Oct 2020 12:02' | (b) (4), (b) (6) System | 03 Oct 2020 16:02:29 |
| | System | 03 Oct 2020 16:02:29 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '03 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 28 Sep 2020 15:45:48 |
| User entered 'Day 7' | System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

HEADACHE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:08', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

FATIGUE

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:10', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:12', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:14', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:16', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

CHILLS

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:18', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered 'None (0)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:21', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered 'No (N)' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8BDF839F-E8ED-4175-8B98-F142E2A90144)', Time: '2020-10-05T08:55:23', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c5b47a9c-22c7-42c1-bd01-7099335c8c75' User entered '05 Oct 2020 08:55' | (b) (4), (b) (6) System | 05 Oct 2020 12:55:25 |
| | System | 05 Oct 2020 12:55:25 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '04 Oct 2020 12:00' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:12:49

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:26:57 |
| User entered '05 Oct 2020 11:59' | (b) (4), (b) (6) System | 28 Sep 2020 15:45:48 |

US3242264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:11:24 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '6 Oct 2020' | Erynn McKinley (b) (4) | 06 Oct 2020 16:11:24 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:11:24 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 06 Oct 2020 16:11:24 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:11:33 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | (b) (4), (b) (6) System | 06 Oct 2020 16:11:33 |

US3242264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 13 Oct 2020 14:40:03 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '13 Oct 2020' | Erynn McKinley (b) (4) | 13 Oct 2020 14:40:03 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) | 13 Oct 2020 14:40:03 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 13 Oct 2020 14:40:03 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 13 Oct 2020 14:40:07 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | System | 13 Oct 2020 14:40:07 |

US3242264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:39 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '21 Oct 2020' | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:39 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:39 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:39 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:41 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | System | 26 Oct 2020 18:03:41 |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:52 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '26 Oct 2020' | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:52 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered 'Clinic (Clinic)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:03:52 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'VISIT3' | System | 26 Oct 2020 18:03:52 |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '26 Oct 2020' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '11:44' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '26 Oct 2020 11:44' | (b) (4), (b) (6) | 26 Oct 2020 18:04:18 |
| | System | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '97.4' F | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered 'Oral (Oral)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '80' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'bpm' | System | 26 Oct 2020 18:04:18 |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '16' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 26 Oct 2020 18:04:18 |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '126' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) | 26 Oct 2020 18:04:18 |
| | System | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '74' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:18 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 26 Oct 2020 18:04:18 |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:22 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:22 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:28 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '26 Oct 2020' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:28 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered '12:14' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:28 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered '26 Oct 2020 12:14' | (b) (4), (b) (6) | 26 Oct 2020 18:04:28 |
| | System | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:21:07 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 26 Oct 2020 18:04:31 |
| | (b) (4) | |

US3242264

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | (b) (4), (b) (6) | 26 Oct 2020 18:04:31 |
| | System | |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 64' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-01T00:01:32', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '454fa658-33f6-4d33-a580-039efc801cc4' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 01 Nov 2020 04:02:31 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-01T00:02:13', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '454fa658-33f6-4d33-a580-039efc801cc4' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 01 Nov 2020 04:02:31 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-01T00:02:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '454fa658-33f6-4d33-a580-039efc801cc4' User entered '01 Nov 2020 00:02:29' | (b) (4), (b) (6) System | 01 Nov 2020 04:02:31 |
| | System | 01 Nov 2020 04:02:31 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered '01 Nov 2020 00:01' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered '05 Nov 2020 23:59' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 71' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-08T16:21:26', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0636d983-dd48-42d4-af0c-1ec198c1f0aa' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 08 Nov 2020 21:21:38 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-08T16:21:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0636d983-dd48-42d4-af0c-1ec198c1f0aa' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 08 Nov 2020 21:21:38 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-08T16:21:35', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0636d983-dd48-42d4-af0c-1ec198c1f0aa' User entered '08 Nov 2020 16:21:35' | (b) (4), (b) (6) System | 08 Nov 2020 21:21:38 |
| | System | 08 Nov 2020 21:21:38 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered '08 Nov 2020 00:01' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered '12 Nov 2020 23:59' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered 'Day 78' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-15T00:06:27', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0ddb1389-29a4-45d6-b662-49c9711432e4' User entered 'No (N)' | (b) (4), (b) (6) System | 15 Nov 2020 05:07:14 |
| | System | 15 Nov 2020 05:07:14 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-15T00:07:02', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0ddb1389-29a4-45d6-b662-49c9711432e4' | (b) (4), (b) (6) | |
| User entered 'No (N)' | System | 15 Nov 2020 05:07:14 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-15T00:07:11', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '0ddb1389-29a4-45d6-b662-49c9711432e4' User entered '15 Nov 2020 00:07:11' | (b) (4), (b) (6) System | 15 Nov 2020 05:07:14 |
| | System | 15 Nov 2020 05:07:14 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered '15 Nov 2020 00:01' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 05:27:02 |
| | (b) (4), (b) (6) | |
| Data entry locked. | System | 01 Sep 2020 14:28:06 |
| User entered '19 Nov 2020 23:59' | System | 01 Sep 2020 14:28:06 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 82' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-23T09:31:57', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b2fd009a-5e17-43f2-9382-297c7ecaf042' | System | 23 Nov 2020 14:33:39 |
| User entered 'Yes (Y)' | System | 23 Nov 2020 14:33:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-23T09:32:12', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b2fd009a-5e17-43f2-9382-297c7ecaf042' | System | 23 Nov 2020 14:33:39 |
| User entered 'No (N)' | System | 23 Nov 2020 14:33:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-23T09:32:22', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b2fd009a-5e17-43f2-9382-297c7ecaf042' | System | 23 Nov 2020 14:33:39 |
| User entered 'No (N)' | System | 23 Nov 2020 14:33:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-23T09:33:27', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b2fd009a-5e17-43f2-9382-297c7ecaf042' | System | 23 Nov 2020 14:33:39 |
| User entered 'No (N)' | System | 23 Nov 2020 14:33:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-23T09:33:35', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b2fd009a-5e17-43f2-9382-297c7ecaf042' | System | 23 Nov 2020 14:33:39 |
| User entered '23 Nov 2020 09:33:35' | System | 23 Nov 2020 14:33:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-26T00:02:05', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a23e8d99-46c4-4988-a386-b4d0545597a3' User entered 'Yes (Y)' | System | 26 Nov 2020 05:04:27 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-26T00:02:22', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a23e8d99-46c4-4988-a386-b4d0545597a3' User entered 'No (N)' | System | 26 Nov 2020 05:04:27 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-26T00:02:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a23e8d99-46c4-4988-a386-b4d0545597a3' User entered 'No (N)' | System | 26 Nov 2020 05:04:27 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-26T00:03:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a23e8d99-46c4-4988-a386-b4d0545597a3' | System | 26 Nov 2020 05:04:27 |
| User entered 'Yes (Y)' | System | 26 Nov 2020 05:04:27 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-26T00:03:30', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a23e8d99-46c4-4988-a386-b4d0545597a3' | System | 26 Nov 2020 05:04:27 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 26 Nov 2020 05:04:27 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-11-26T00:04:18', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a23e8d99-46c4-4988-a386-b4d0545597a3' User entered '26 Nov 2020 00:04:18' | System | 26 Nov 2020 05:04:27 |
| | System | 26 Nov 2020 05:04:27 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-03T12:59:35', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'eaab3a8f-ce79-4e7f-89d5-ef575fb9ac9c' | System | 03 Dec 2020 17:59:48 |
| User entered 'No (N)' | System | 03 Dec 2020 17:59:48 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-03T12:59:42', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'eaab3a8f-ce79-4e7f-89d5-ef575fb9ac9c' | System | 03 Dec 2020 17:59:48 |
| User entered 'No (N)' | System | 03 Dec 2020 17:59:48 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-03T12:59:46', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'eaab3a8f-ce79-4e7f-89d5-ef575fb9ac9c' User entered '03 Dec 2020 12:59:46' | System | 03 Dec 2020 17:59:48 |
| | System | 03 Dec 2020 17:59:48 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-11T09:09:31', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b6f99b7b-1467-49c5-a7c4-eed7a5a1502d' User entered 'No (N)' | System | 11 Dec 2020 14:09:42 |
| | System | 11 Dec 2020 14:09:42 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-11T09:09:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b6f99b7b-1467-49c5-a7c4-eed7a5a1502d' User entered 'No (N)' | System | 11 Dec 2020 14:09:42 |
| | System | 11 Dec 2020 14:09:42 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-11T09:09:38', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'b6f99b7b-1467-49c5-a7c4-eed7a5a1502d' User entered '11 Dec 2020 09:09:38' | System | 11 Dec 2020 14:09:42 |
| | System | 11 Dec 2020 14:09:42 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-17T12:07:55', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a0aabb18-8d74-4de8-8529-489f76c9a342' | System | 17 Dec 2020 17:08:37 |
| User entered 'No (N)' | System | 17 Dec 2020 17:08:37 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-17T12:08:23', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a0aabb18-8d74-4de8-8529-489f76c9a342' | System | 17 Dec 2020 17:08:37 |
| User entered 'No (N)' | System | 17 Dec 2020 17:08:37 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0AB9030F-05B9-4E52-9528-5346C5AFD41E)', Time: '2020-12-17T12:08:36', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'a0aabb18-8d74-4de8-8529-489f76c9a342' User entered '17 Dec 2020 12:08:36' | System | 17 Dec 2020 17:08:37 |
| | System | 17 Dec 2020 17:08:37 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2020-12-28T10:56:01', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '93c8062b-1322-4480-9e14-0379a6196da2' | System | 28 Dec 2020 15:56:09 |
| User entered 'No (N)' | System | 28 Dec 2020 15:56:09 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2020-12-28T10:56:04', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '93c8062b-1322-4480-9e14-0379a6196da2' | System | 28 Dec 2020 15:56:09 |
| User entered 'No (N)' | System | 28 Dec 2020 15:56:09 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2020-12-28T10:56:07', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '93c8062b-1322-4480-9e14-0379a6196da2' | System | 28 Dec 2020 15:56:09 |
| User entered '28 Dec 2020 10:56:07' | System | 28 Dec 2020 15:56:09 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2020-12-31T00:13:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '476f0176-0666-4d6a-8743-201f4f5e0ef9' User entered 'No (N)' | System | 31 Dec 2020 05:13:53 |
| | System | 31 Dec 2020 05:13:53 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2020-12-31T00:13:07', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '476f0176-0666-4d6a-8743-201f4f5e0ef9' User entered 'No (N)' | System | 31 Dec 2020 05:13:53 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2020-12-31T00:13:49', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '476f0176-0666-4d6a-8743-201f4f5e0ef9' User entered '31 Dec 2020 00:13:49' | System | 31 Dec 2020 05:13:53 |
| | System | 31 Dec 2020 05:13:53 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-07T00:01:33', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '917cb57f-6641-4ac6-b683-eddf6ccb0439' User entered 'No (N)' | System | 07 Jan 2021 05:02:00 |
| | System | 07 Jan 2021 05:02:00 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-07T00:01:43', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '917cb57f-6641-4ac6-b683-eddf6ccb0439' User entered 'No (N)' | System | 07 Jan 2021 05:02:00 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-07T00:01:46', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '917cb57f-6641-4ac6-b683-eddf6ccb0439' User entered '07 Jan 2021 00:01:46' | System | 07 Jan 2021 05:02:00 |
| | System | 07 Jan 2021 05:02:00 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-14T00:01:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef9720d6-0f0c-4dc6-9d1e-b29cb49f0479' | System | 14 Jan 2021 05:02:25 |
| User entered 'No (N)' | System | 14 Jan 2021 05:02:25 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-14T00:01:56', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef9720d6-0f0c-4dc6-9d1e-b29cb49f0479' | System | 14 Jan 2021 05:02:25 |
| User entered 'No (N)' | System | 14 Jan 2021 05:02:25 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-14T00:02:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ef9720d6-0f0c-4dc6-9d1e-b29cb49f0479' User entered '14 Jan 2021 00:02:00' | System | 14 Jan 2021 05:02:25 |
| | System | 14 Jan 2021 05:02:25 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-21T00:01:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '02d3f2ef-4aea-48e5-901d-4bc4684d5e87' | System | 21 Jan 2021 05:02:26 |
| User entered 'No (N)' | System | 21 Jan 2021 05:02:26 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-21T00:01:48', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '02d3f2ef-4aea-48e5-901d-4bc4684d5e87' | System | 21 Jan 2021 05:02:26 |
| User entered 'Yes (Y)' | System | 21 Jan 2021 05:02:26 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-21T00:02:02', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '02d3f2ef-4aea-48e5-901d-4bc4684d5e87' | System | 21 Jan 2021 05:02:26 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 21 Jan 2021 05:02:26 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-21T00:02:09', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '02d3f2ef-4aea-48e5-901d-4bc4684d5e87' | System | 21 Jan 2021 05:02:26 |
| User entered '21 Jan 2021 00:02:09' | System | 21 Jan 2021 05:02:26 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-28T00:01:44', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '05961af7-511c-4fd0-97e1-1a9a2a883598' | System | 28 Jan 2021 05:02:31 |
| User entered 'No (N)' | System | 28 Jan 2021 05:02:31 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-28T00:01:53', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '05961af7-511c-4fd0-97e1-1a9a2a883598' | System | 28 Jan 2021 05:02:31 |
| User entered 'No (N)' | System | 28 Jan 2021 05:02:31 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-01-28T00:01:57', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '05961af7-511c-4fd0-97e1-1a9a2a883598' User entered '28 Jan 2021 00:01:57' | System | 28 Jan 2021 05:02:31 |
| | System | 28 Jan 2021 05:02:31 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-04T00:01:24', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e1e5eb5e-796c-4fda-9163-6b228569dbb5' | System | 04 Feb 2021 06:02:07 |
| User entered 'Yes (Y)' | System | 04 Feb 2021 06:02:07 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-04T00:01:28', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e1e5eb5e-796c-4fda-9163-6b228569dbb5' | System | 04 Feb 2021 06:02:07 |
| User entered 'No (N)' | System | 04 Feb 2021 06:02:07 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-04T00:01:32', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e1e5eb5e-796c-4fda-9163-6b228569dbb5' User entered 'No (N)' | System | 04 Feb 2021 06:02:07 |
| | System | 04 Feb 2021 06:02:07 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-04T00:01:41', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e1e5eb5e-796c-4fda-9163-6b228569dbb5' | System | 04 Feb 2021 06:02:07 |
| User entered 'Yes (Y)' | System | 04 Feb 2021 06:02:07 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-04T00:01:45', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e1e5eb5e-796c-4fda-9163-6b228569dbb5' | System | 04 Feb 2021 06:02:07 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 04 Feb 2021 06:02:07 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-04T00:01:50', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e1e5eb5e-796c-4fda-9163-6b228569dbb5' User entered '04 Feb 2021 00:01:50' | System | 04 Feb 2021 06:02:07 |
| | System | 04 Feb 2021 06:02:07 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-11T18:23:16', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '002af7a7-1a3a-4603-9c90-abc86c48bc97' User entered 'No (N)' | System | 12 Feb 2021 00:25:14 |
| | System | 12 Feb 2021 00:25:14 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-11T18:23:29', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '002af7a7-1a3a-4603-9c90-abc86c48bc97' User entered 'No (N)' | System | 12 Feb 2021 00:25:14 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-11T18:23:34', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '002af7a7-1a3a-4603-9c90-abc86c48bc97' | System | 12 Feb 2021 00:25:14 |
| User entered '11 Feb 2021 18:23:34' | System | 12 Feb 2021 00:25:14 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-18T19:25:44', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7f4a7f1f-1148-4ea8-8234-7b22080152a0' User entered 'No (N)' | System | 19 Feb 2021 01:25:59 |
| | System | 19 Feb 2021 01:25:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-18T19:25:51', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7f4a7f1f-1148-4ea8-8234-7b22080152a0' User entered 'No (N)' | System | 19 Feb 2021 01:25:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-18T19:25:57', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '7f4a7f1f-1148-4ea8-8234-7b22080152a0' User entered '18 Feb 2021 19:25:57' | System | 19 Feb 2021 01:25:59 |
| | System | 19 Feb 2021 01:25:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-26T21:39:43-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c67b1e04-af1f-41af-a302-0dfe7d483e97' | System | 27 Feb 2021 03:39:55 |
| User entered 'No (N)' | System | 27 Feb 2021 03:39:55 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-26T21:39:47-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c67b1e04-af1f-41af-a302-0dfe7d483e97' | System | 27 Feb 2021 03:39:55 |
| User entered 'No (N)' | System | 27 Feb 2021 03:39:55 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-26T21:39:50-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'c67b1e04-af1f-41af-a302-0dfe7d483e97' | System | 27 Feb 2021 03:39:55 |
| User entered '27 Feb 2021 03:39:50' | System | 27 Feb 2021 03:39:55 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-04T08:47:54-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'aacad0cc-5f74-436e-9af8-24620338454d' | System | 08 Mar 2021 02:29:21 |
| User entered 'No (N)' | System | 08 Mar 2021 02:29:21 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-04T08:47:57-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'aacad0cc-5f74-436e-9af8-24620338454d' | System | 08 Mar 2021 02:29:21 |
| User entered 'No (N)' | System | 08 Mar 2021 02:29:21 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-04T08:47:59-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'aacad0cc-5f74-436e-9af8-24620338454d' | System | 08 Mar 2021 02:29:21 |
| User entered '04 Mar 2021 08:47:59' | System | 08 Mar 2021 02:29:21 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-14T00:19:05-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8dfa46e8-81e9-4ebd-9936-25333e278135' | System | 14 Mar 2021 06:19:20 |
| User entered 'No (N)' | System | 14 Mar 2021 06:19:20 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-14T00:19:11-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8dfa46e8-81e9-4ebd-9936-25333e278135' | System | 14 Mar 2021 06:19:20 |
| User entered 'No (N)' | System | 14 Mar 2021 06:19:20 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-14T00:19:14-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '8dfa46e8-81e9-4ebd-9936-25333e278135' | System | 14 Mar 2021 06:19:20 |
| User entered '14 Mar 2021 00:19:14' | System | 14 Mar 2021 06:19:20 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:05:29-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered 'Yes (Y)' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:05:36-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered 'No (N)' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:05:56-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered 'Yes (Y)' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '1' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '1' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '1' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Muscle aches](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Body aches](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '1' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '1' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[New loss of taste](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[New loss of smell](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Sore throat](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Congestion](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Runny nose](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered '0' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:27-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:35-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' | System | 18 Mar 2021 05:06:51 |
| User entered 'No (N)' | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-18T00:06:40-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '1f0bb262-4403-46ca-96c7-baaea6fcc9e6' User entered '18 Mar 2021 00:06:40' | System | 18 Mar 2021 05:06:51 |
| | System | 18 Mar 2021 05:06:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-25T00:56:05-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dc0fe94c-6cc7-49b9-988d-87551f7f7462' | System | 25 Mar 2021 05:56:30 |
| User entered 'No (N)' | System | 25 Mar 2021 05:56:30 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-25T00:56:19-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dc0fe94c-6cc7-49b9-988d-87551f7f7462' | System | 25 Mar 2021 05:56:30 |
| User entered 'No (N)' | System | 25 Mar 2021 05:56:30 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-03-25T00:56:24-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'dc0fe94c-6cc7-49b9-988d-87551f7f7462' | System | 25 Mar 2021 05:56:30 |
| User entered '25 Mar 2021 00:56:24' | System | 25 Mar 2021 05:56:30 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-01T00:43:21-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fc94a65d-a9f0-4265-bf6a-38a33fc1ccc1' User entered 'No (N)' | System | 01 Apr 2021 05:43:39 |
| | System | 01 Apr 2021 05:43:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-01T00:43:33-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fc94a65d-a9f0-4265-bf6a-38a33fc1ccc1' | System | 01 Apr 2021 05:43:39 |
| User entered 'No (N)' | System | 01 Apr 2021 05:43:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-01T00:43:37-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'fc94a65d-a9f0-4265-bf6a-38a33fc1ccc1' User entered '01 Apr 2021 00:43:37' | System | 01 Apr 2021 05:43:39 |
| | System | 01 Apr 2021 05:43:39 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-12T10:56:49-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ddb2b701-8f0e-4cfc-9dc1-870fadba8b1a' User entered 'No (N)' | System | 12 Apr 2021 15:56:59 |
| | System | 12 Apr 2021 15:56:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-12T10:56:53-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ddb2b701-8f0e-4cfc-9dc1-870fadba8b1a' User entered 'No (N)' | System | 12 Apr 2021 15:56:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-12T10:56:56-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'ddb2b701-8f0e-4cfc-9dc1-870fadba8b1a' | System | 12 Apr 2021 15:56:59 |
| User entered '12 Apr 2021 10:56:56' | System | 12 Apr 2021 15:56:59 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-15T02:00:29-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3f35b219-7771-4116-badf-72d8316cf9e3' | System | 15 Apr 2021 07:00:43 |
| User entered 'No (N)' | System | 15 Apr 2021 07:00:43 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-15T02:00:36-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3f35b219-7771-4116-badf-72d8316cf9e3' | System | 15 Apr 2021 07:00:43 |
| User entered 'No (N)' | System | 15 Apr 2021 07:00:43 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-15T02:00:39-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '3f35b219-7771-4116-badf-72d8316cf9e3' | System | 15 Apr 2021 07:00:43 |
| User entered '15 Apr 2021 02:00:39' | System | 15 Apr 2021 07:00:43 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-22T00:02:24-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '5007c863-7ccf-4793-8789-25d0bc6501e1' User entered 'No (N)' | System | 22 Apr 2021 05:02:51 |
| | System | 22 Apr 2021 05:02:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-22T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '5007c863-7ccf-4793-8789-25d0bc6501e1' | System | 22 Apr 2021 05:02:51 |
| User entered 'No (N)' | System | 22 Apr 2021 05:02:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-04-22T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: '5007c863-7ccf-4793-8789-25d0bc6501e1' User entered '22 Apr 2021 00:02:35' | System | 22 Apr 2021 05:02:51 |
| | System | 22 Apr 2021 05:02:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-05-01T09:19:39-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f2f80cab-87c8-4dd3-a040-797e77fe5d4a' | System | 01 May 2021 14:19:51 |
| User entered 'No (N)' | System | 01 May 2021 14:19:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-05-01T09:19:43-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f2f80cab-87c8-4dd3-a040-797e77fe5d4a' | System | 01 May 2021 14:19:51 |
| User entered 'No (N)' | System | 01 May 2021 14:19:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-05-01T09:19:48-05:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'f2f80cab-87c8-4dd3-a040-797e77fe5d4a' | System | 01 May 2021 14:19:51 |
| User entered '01 May 2021 09:19:48' | System | 01 May 2021 14:19:51 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '20 Oct 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '24 Oct 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '27 Oct 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '31 Oct 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '03 Nov 2022 00:01' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:12:49

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 21:31:32 |
| Amendment Manager: User entered '07 Nov 2022 23:59' | System | 19 Nov 2020 21:31:32 |

US3242264

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:12:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 15:13:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-28T02:04:46-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e064ea8f-3e2c-4713-9f55-aa05ea6f892b' | (b) (4), (b) (6) | |
| User entered 'Yes (Y)' | System | 28 Feb 2021 08:05:15 |

US3242264

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:12:49

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 15:13:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-28T02:04:58-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e064ea8f-3e2c-4713-9f55-aa05ea6f892b' | (b) (4), (b) (6) | 28 Feb 2021 08:05:15 |
| User entered 'No (N)' | System | 28 Feb 2021 08:05:15 |

US3242264

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:12:49

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 15:13:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C00B3B0C-76B4-41E9-BB6C-CF0A859BE0E3)', Time: '2021-02-28T02:05:06-06:00', User OID: 'PatientReportedOutcome (US3242264)', ODM File OID: 'e064ea8f-3e2c-4713-9f55-aa05ea6f892b' User entered '28 Feb 2021 08:05:06' | (b) (4), (b) (6) System | 28 Feb 2021 08:05:15 |
| | System | 28 Feb 2021 08:05:15 |

US3242264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:34:44 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered '24 Nov 2020' | Erynn McKinley (b) (4) | 24 Nov 2020 21:34:44 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:34:44 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 24 Nov 2020 21:34:44 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:34:48 |
| | (b) (4) | |

US3242264

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 17:50:46 |
| User entered 'I' | (b) (4), (b) (6) | 24 Nov 2020 21:34:48 |
| | System | |

US3242264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 28 Dec 2020 21:46:19 |

US3242264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered '28 Dec 2020' | Erynn McKinley (b) (4) (b) (4) | 28 Dec 2020 21:46:19 |

US3242264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) (b) (4) | 28 Dec 2020 21:46:19 |

US3242264

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered empty. | Erynn McKinley (b) (4) (b) (4) | 28 Dec 2020 21:46:19 |

US3242264

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 28 Dec 2020 21:46:22 |

US3242264

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User entered 'I' | (b) (4), (b) (6) System | 28 Dec 2020 21:46:22 |

US3242264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 25 Jan 2021 15:01:57 |

US3242264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered '25 Jan 2021' | Erynn McKinley (b) (4) (b) (4) | 25 Jan 2021 15:01:57 |

US3242264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) (b) (4) | 25 Jan 2021 15:01:57 |

US3242264

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered empty. | Erynn McKinley (b) (4) (b) (4) | 25 Jan 2021 15:01:57 |

US3242264

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 25 Jan 2021 15:02:01 |

US3242264

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User entered 'I' | (b) (4), (b) (6) System | 25 Jan 2021 15:02:01 |

US3242264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 22 Feb 2021 16:52:11 |

US3242264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| User entered '22 Feb 2021' | Erynn McKinley (b) (4) (b) (4) | 22 Feb 2021 16:52:11 |

US3242264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) (b) (4) | 22 Feb 2021 16:52:11 |

US3242264

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| User entered empty. | Erynn McKinley (b) (4) (b) (4) | 22 Feb 2021 16:52:11 |

US3242264

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 22 Feb 2021 16:52:16 |

US3242264

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 16:22:21 |
| User entered 'I' | (b) (4), (b) (6) System | 22 Feb 2021 16:52:16 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:12:49

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:32 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 14 Oct 2020 19:32:34 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:12:49

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:32 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered '11:27' | Donna Toepfer (b) (4) | 14 Oct 2020 19:32:34 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:12:49

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:32 |
| User entered '14 Oct 2020 11:27' | (b) (4), (b) (6) System | 14 Oct 2020 19:32:34 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:12:49

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:32 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Safety Call (Safety Call)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:32:34 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:12:49

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:32 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:32:34 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Day 1 (Day 1)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Date](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '10 Oct 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:25:20 |
| User entered '13 Oct 2020' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

O2 Saturation

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| User closed query 'Per CDM: It appears that O2 Saturation and Temperature were not provided for Day 1- Day 4. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 14:27:15 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:38 |
| Query 'Per CDM: It appears that O2 Saturation and Temperature were not provided for Day 1- Day 4. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'updated' (Site from DM). | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:26 |
| User opened query 'Per CDM: It appears that O2 Saturation and Temperature were not provided for Day 1- Day 4. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 11:59:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User entered '%' | (b) (4), (b) (6) | 07 Jan 2021 14:13:38 |
| User entered empty. | System | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Temperature](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:38 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:25:20 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:25:20 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:25:20 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:12:49

[Sore Throat](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 14 Oct 2020 19:37:16 |
| User entered empty. | Donna Toepfer (b) (4) | 14 Oct 2020 19:33:31 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Day 2 (Day 2)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Date](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '11 Oct 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:31:02 |
| User entered '99' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 07 Jan 2021 14:13:50 |
| User entered empty. | System | 22 Oct 2020 18:31:02 |
| User entered '%' | System | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

Temperature

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:50 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:13:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:31:02 |
| User entered '99.9' F | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered 'Moderate (Moderate)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Body Aches](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered 'Moderate (Moderate)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:10 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:12:49

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:36:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Day 3 (Day 3)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Date](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '12 Oct 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:54 |
| User entered '15 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:03 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:31:17 |
| User entered '99' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 07 Jan 2021 14:14:03 |
| User entered empty. | System | 22 Oct 2020 18:31:17 |
| User entered '%' | System | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

Temperature

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:03 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:31:17 |
| User entered '99.1' F | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:54 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Body Aches](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:54 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:54 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:26:54 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:12:49

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:15 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Symptom Day](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Day 4 (Day 4)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:32:17 |
| User entered 'Day 3 (Day 3)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Date](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '13 Oct 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:32:17 |
| User entered '16 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:32:17 |
| User entered '100' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User entered '%' | System | 07 Jan 2021 14:14:21 |
| User entered empty. | System | 22 Oct 2020 18:32:17 |
| User entered '%' | System | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

Temperature

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:36:37 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:21 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Donna Toepfer (b) (4) | 07 Jan 2021 14:14:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:32:17 |
| User entered '98.4' F | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Oct 2020 18:32:17 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |
| | | |
| | | |

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Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:12:49

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:19:59 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Day 5 (Day 5)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '99' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User entered '%' | (b) (4), (b) (6) System | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '99.9' F | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Moderate (Moderate)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Moderate (Moderate)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Moderate (Moderate)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:12:49

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:40:20 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Day 6 (Day 6)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '15 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '99' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User entered '%' | (b) (4), (b) (6) System | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '99.1' F | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Mild (Mild)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:12:49

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:41:12 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User entered 'Day 7 (Day 7)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '16 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '100' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User entered '%' | (b) (4), (b) (6) System | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '98.4' F | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:12:49

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:37 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (None)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:42:04 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Date of Test](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |
| | | |
| | | |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:21:22 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:12:49

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:44 |
| User entered '0' | (b) (4), (b) (6) System | 22 Oct 2020 18:21:22 |

US3242264

Folder: Covid-19 Assessment 14 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:12:49

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 22:17:50 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 14 Oct 2020 19:38:04 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:12:49

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |
| | | |
| | | |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:12:49

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |
| | | |
| | | |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the tracking number. Please provide the Accession number which starts with "1F" in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). Query 'Per GCL Lab Reconciliation Requery: Saliva: Donna Toepfer (b) (4) Per response, thank you for confirming the tracking number. Please provide the Accession number which starts with "1F" in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with '1F60ECH' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 25 Jan 2021 10:41:37 |
| User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response, thank you for confirming the tracking number. Please provide the Accession number which starts with "1F" in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 09:08:29 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 09:08:29 |
| Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with '9179 0331 4590' (Site from DM). | Donna Toepfer (b) (4) | 13 Jan 2021 12:54:49 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 06:32:42 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 08:41:34 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'confirmed receipt from lab' (Site from DM). | Donna Toepfer (b) (4) | 08 Dec 2020 13:18:36 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16OCT2020 is recorded under Illness Visit Day 3 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 08:40:02 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User closed query 'Per GCL Lab Recon: Saliva: Sample dated 16OCT2020 for Day 3 is recorded in EDC central lab, however same is reported with 20OCT2020 for Day 3 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 16:20:12 |
| Query 'Per GCL Lab Recon: Saliva: Sample dated 16OCT2020 for Day 3 is recorded in EDC central lab, however same is reported with 20OCT2020 for Day 3 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' answered with 'value is correct 16 Oct 2020' (Site from DM). | Donna Toepfer (b) (4) | 30 Oct 2020 13:10:32 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User opened query 'Per GCL Lab Recon: Saliva: Sample dated 16OCT2020 for Day 3 is recorded in EDC central lab, however same is reported with 20OCT2020 for Day 3 in PPD Central lab. Please reconcile and update if applicable, else clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 06:17:00 |
| User entered '16 Oct 2020' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:12:49

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 05:57:12 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'updated' (Site from DM). | Donna Toepfer (b) (4) | 24 Nov 2020 15:51:45 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 06:35:06 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 20OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 24 Nov 2020 06:34:55 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 20OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Only Saliva collected per source is 16Oct2020' (Site from DM). | Donna Toepfer (b) (4) | 06 Nov 2020 13:15:44 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 20OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 06:46:33 |
| User accepted default value 'Day 5 (Day 5)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:12:49

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 02 Mar 2021 22:07:21 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 02 Mar 2021 17:46:46 |
| Signature has been broken. | Donna Toepfer (b) (4) | 02 Mar 2021 17:46:46 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 02 Mar 2021 17:46:46 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:39:29 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) | 24 Nov 2020 15:51:40 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 24 Nov 2020 15:51:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|--|--|
| User closed query 'Per GCL LAB reconciliation: Saliva: Sample dated 20OCT2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). User signature succeeded. | (b) (4), (b) (6) [REDACTED] Nathan Segall (b) (4) [REDACTED] [REDACTED] | 05 Mar 2021 08:28:52 02 Mar 2021 22:07:21 |
| Query 'Per GCL LAB reconciliation: Saliva: Sample dated 20OCT2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'updated' (Site from DM). DataPoint Un-verified. | Donna Toepfer (b) (4) [REDACTED] [REDACTED] Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 02 Mar 2021 17:46:53 02 Mar 2021 17:46:46 |
| Signature has been broken. | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 02 Mar 2021 17:46:46 |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 02 Mar 2021 17:46:46 |
| User opened query 'Per GCL LAB reconciliation: Saliva: Sample dated 20OCT2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM). User signature succeeded. | (b) (4), (b) (6) [REDACTED] Nathan Segall (b) (4) [REDACTED] [REDACTED] | 26 Feb 2021 06:59:40 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) [REDACTED] [REDACTED] | 28 Jan 2021 19:39:29 |
| DataPoint Un-verified. | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 24 Nov 2020 15:51:40 |
| User entered '20 Oct 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 24 Nov 2020 15:51:40 |
| DataPoint Verified. | (b) (4), (b) (6) [REDACTED] [REDACTED] | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:12:49

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |
| | | |
| | | |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:12:49

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | Donna Toepfer (b) (4) (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:12:49

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |
| | | |
| | | |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:12:49

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | Donna Toepfer (b) (4) (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:12:49

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |
| | | |
| | | |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:12:49

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | Donna Toepfer (b) (4) (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:12:49

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |
| | | |
| | | |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:12:49

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | Donna Toepfer (b) (4) (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:12:49

[Visit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |
| | | |
| | | |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:12:49

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'NA (COVID-19 Negative) (NA)' | Donna Toepfer (b) (4) (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 28 Oct 2020 20:00:19 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 28 Oct 2020 14:03:38 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 28 Oct 2020 14:03:38 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Clinic (Clinic)' | Donna Toepfer (b) (4) | 28 Oct 2020 14:03:38 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User entered 'SICKD1' | (b) (4), (b) (6) System | 28 Oct 2020 14:03:38 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '12:28' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User entered '14 Oct 2020 12:28' | (b) (4), (b) (6) System | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Height (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| User entered '72' in | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| DataPoint set to visible. | System | 28 Oct 2020 14:03:38 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '216' lb | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| DataPoint set to visible. | System | 28 Oct 2020 14:03:38 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '98.6' F | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Oral (Oral)' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered empty. | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '72' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User entered 'bpm' | (b) (4), (b) (6) System | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| User entered '18' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| User entered '128' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '80' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:28 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 28 Oct 2020 14:04:28 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 01 May 2021 21:49:44 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:12:49

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) (b) (4), (b) (6) | 01 May 2021 21:49:44 |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:43 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered '14 Oct 2020' | Donna Toepfer (b) (4) | 28 Oct 2020 14:04:43 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:12:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| | | |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 28 Oct 2020 14:05:00 |
| | | |
| | | |

US3242264

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:12:49

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:49:44 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:07:59 |
| User closed query 'Per GCL Lab Reconciliation: Please confirm date of immunologic sample collection as date is discrepant with date of illness visit' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 16:34:22 |
| Query 'Per GCL Lab Reconciliation: Please confirm date of immunologic sample collection as date is discrepant with date of illness visit' answered with 'updated' (Site from DM). | Donna Toepfer (b) (4) | 30 Oct 2020 13:12:36 |
| User entered '14 Oct 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 30 Oct 2020 13:12:31 |
| User opened query 'Per GCL Lab Reconciliation: Please confirm date of immunologic sample collection as date is discrepant with date of illness visit' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 00:04:01 |
| User entered '28 Oct 2020' | Donna Toepfer (b) (4) | 28 Oct 2020 14:05:00 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:08:59 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:08:59 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Clinic (Clinic)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:08:59 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'UNBLND_DECIDE' | (b) (4), (b) (6) System | 15 Feb 2021 15:08:59 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:18 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '0' WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 07:44:59 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:18 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 07:44:59 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:18 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Placebo (Placebo)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:18 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Placebo (Placebo)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:18 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Placebo (Placebo)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:18 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:18 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '1' | (b) (4), (b) (6) System | 15 Feb 2021 15:09:18 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:12:49

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'I' | (b) (4), (b) (6) System | 15 Feb 2021 15:09:18 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered missing code ND - Not Done. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

Weight

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered missing code ND - Not Done. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User entered empty. | System | 15 Feb 2021 15:11:26 |
| DataPoint set to visible. | System | 15 Feb 2021 15:09:18 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered missing code ND - Not Done. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

Weight

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered missing code ND - Not Done. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User entered empty. | System | 15 Feb 2021 15:11:26 |
| DataPoint set to visible. | System | 15 Feb 2021 15:09:18 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User accepted default value 'Pre-Dose (PREDOSE)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '09:16' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Feb 2021 09:16' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '97.4' F | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Oral (Oral)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '72' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'bpm' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '16' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '120' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '72' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered missing code ND - Not Done. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

Weight

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered missing code ND - Not Done. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:12:49

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User entered empty. | System | 15 Feb 2021 15:11:26 |
| DataPoint set to visible. | System | 15 Feb 2021 15:09:18 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '10:02' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Feb 2021 10:02' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '97.6' F | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Oral (Oral)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '72' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'bpm' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '16' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '122' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '78' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:26 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:26 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:33 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:33 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:48 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:48 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:48 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mRNA-1273' | (b) (4), (b) (6) | 15 Feb 2021 15:11:48 |
| DataPoint set to visible. | System | 15 Feb 2021 15:09:18 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:48 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '09:32' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:48 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Feb 2021 09:32' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:48 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Left Arm (LEFT ARM)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:11:48 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'ONCE' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:48 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'INTRAMUSCULAR' | (b) (4), (b) (6) System | 15 Feb 2021 15:11:48 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:38 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:38 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '08:56' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:38 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:12:49

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Feb 2021 08:56' | (b) (4), (b) (6) System | 15 Feb 2021 15:09:38 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:12:49

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:49 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:12:49

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '15 Feb 2021' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:49 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:12:49

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered '08:53' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:49 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:12:49

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Feb 2021 08:53' | (b) (4), (b) (6) System | 15 Feb 2021 15:09:49 |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 17 Feb 2021 17:23:10 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Feb 2021 15:09:52 |
| | (b) (4) | |

US3242264

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '1' | (b) (4), (b) (6) System | 15 Feb 2021 15:09:52 |

US3242264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 22 Feb 2021 16:53:01 |

US3242264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| | | |
| User entered '22 Feb 2021' | Erynn McKinley (b) (4) | 22 Feb 2021 16:53:01 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) (b) (4) | 22 Feb 2021 16:53:01 |

US3242264

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 22 Feb 2021 16:53:01 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 02 Mar 2021 22:07:21 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 22 Feb 2021 16:53:11 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'I' | (b) (4), (b) (6) System | 22 Feb 2021 16:53:11 |

US3242264

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User entered 'I' | System | 22 Feb 2021 16:53:11 |
| DataPoint set to visible. | System | 22 Feb 2021 16:53:11 |

US3242264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:24:14 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '15 Mar 2021' | Erynn McKinley (b) (4) | 15 Mar 2021 14:24:14 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'Clinic (Clinic)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:24:14 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:12:49

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'OLD29' | (b) (4), (b) (6) System | 15 Mar 2021 14:24:14 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4) | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| User entered '15 Mar 2021' | Erynn McKinley (b) (4) (b) (4) | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '08:26' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Mar 2021 08:26' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '97.6' F | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'Oral (Oral)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '72' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'bpm' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '18' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '124' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '68' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) Erynn McKinley (b) (4) (b) (4) | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| User entered '15 Mar 2021' | Erynn McKinley (b) (4) (b) (4) | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '10:06' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Mar 2021 10:06' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| | | |
| User entered '97.8' F | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'Oral (Oral)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '68' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'bpm' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '16' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'breaths/min' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '118' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '74' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:30 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:12:49

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mmHg' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:30 |

US3242264

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:33 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:12:49

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:33 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:47 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:47 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:47 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'mRNA-1273' | (b) (4), (b) (6) | 15 Mar 2021 14:25:47 |
| DataPoint set to visible. | System | 22 Feb 2021 16:53:11 |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '15 Mar 2021' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:47 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered '09:33' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:47 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered '15 Mar 2021 09:33' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:47 |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| User entered 'Left Arm (LEFT ARM)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:25:47 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'ONCE' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:47 |

US3242264

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:12:49

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'INTRAMUSCULAR' | (b) (4), (b) (6) System | 15 Mar 2021 14:25:47 |

US3242264

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 15 Mar 2021 16:07:14 |
| | | |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 15 Mar 2021 14:26:39 |
| | (b) (4) | |

US3242264

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'I' | (b) (4), (b) (6) System | 15 Mar 2021 14:26:39 |

US3242264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 25 Mar 2021 18:15:56 |
| | | |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 22 Mar 2021 16:32:02 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 25 Mar 2021 18:15:56 |
| | | |
| User entered '22 Mar 2021' | Erynn McKinley (b) (4) | 22 Mar 2021 16:32:02 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 25 Mar 2021 18:15:56 |
| | | |
| User entered 'Contact Made (CONTACT MADE)' | Erynn McKinley (b) (4) | 22 Mar 2021 16:32:02 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:12:49

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 25 Mar 2021 18:15:56 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 22 Mar 2021 16:32:02 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 25 Mar 2021 18:15:56 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 22 Mar 2021 16:32:07 |
| | (b) (4) | |

US3242264

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:12:49

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 04:51:29 |
| User entered 'I' | (b) (4), (b) (6) System | 22 Mar 2021 16:32:07 |

US3242264

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:12:49

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 04:33:25 |
| User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 10:00:02 |
| Query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'subject states, had Covid swab before going to visit family, swab was negative.' (Site from DM). | Donna Toepfer (b) (4) | 30 Mar 2021 12:27:53 |
| User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 26 Mar 2021 10:10:01 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |

US3242264

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:12:49

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| User entered 'Yes (Y)' reason for change: Data Entry Error | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 22 Oct 2020 18:21:42 |
| User entered 'No (N)' | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 01 Sep 2020 14:25:10 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| | | |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 18 Nov 2020 19:47:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\23.0. | Coder Import (b) (4) | 13 Nov 2020 13:35:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | (b) (4) | 13 Nov 2020 13:35:45 |
| Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'updated per source, was covid symptom, but subject was negative for covid' (Site from DM). | Donna Toepfer (b) (4) | 13 Nov 2020 13:35:17 |
| Data point term sent to Coder | System | 13 Nov 2020 13:34:50 |
| Coding entries removed. | Donna Toepfer (b) (4) | 13 Nov 2020 13:34:49 |
| User entered 'Viral Syndrome' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 13 Nov 2020 13:34:49 |
| User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 21:44:56 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0. | Coder Import (b) (4) | 29 Oct 2020 20:07:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 29 Oct 2020 20:07:45 |
| Data point term sent to Coder | System | 28 Oct 2020 20:58:07 |
| Coding entries removed. | Donna Toepfer (b) (4) | 28 Oct 2020 20:57:34 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User entered 'Vomitting' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 28 Oct 2020 20:57:34 |
| | | |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Oct 2020 18:29:36 |
| | | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Oct 2020 18:29:36 |
| | | |
| Data point term sent to Coder | System | 22 Oct 2020 18:23:10 |
| User entered 'Possible Covid-19' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |
| | | |
| | | |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '10 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User entered empty. | System | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '17 Oct 2020' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User entered empty. | System | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Not Related (NOT RELATED)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Not Related (NOT RELATED)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'None (NONE)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'I' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User entered '0' | System | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |
| User entered '0' | System | 22 Oct 2020 18:22:33 |

US3242264

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:12:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:30 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Broken nose - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 17:55:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Nov 2020 17:55:08 |
| Data point term sent to Coder | System | 24 Nov 2020 16:45:06 |
| User entered 'Broken Nose' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '20 Nov 2020' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User entered empty. | System | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'No (N)' reason for change: Data Entry Error | Erynn McKinley (b) (4) | 25 Jan 2021 15:03:29 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '30 Nov 2020' reason for change: Data Entry Error | Erynn McKinley (b) (4) | 25 Jan 2021 15:03:29 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User entered empty. | System | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Severity](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error | Erynn McKinley (b) (4) | 24 Nov 2020 21:37:17 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 24 Nov 2020 16:44:32 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 24 Nov 2020 16:44:32 |
| User entered 'No (N)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:32 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 24 Nov 2020 16:44:23 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Not Related (NOT RELATED)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Not Related (NOT RELATED)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

None

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' reason for change: Data Entry Error | Erynn McKinley (b) (4) | 24 Nov 2020 21:37:17 |
| User entered '1' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '1' reason for change: Data Entry Error | Erynn McKinley (b) (4) | 24 Nov 2020 21:37:17 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Erynn McKinley (b) (4) | 25 Jan 2021 15:03:29 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User entered '0' | System | 24 Nov 2020 16:44:32 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| User entered 'I' | System | 24 Nov 2020 16:44:23 |

US3242264

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:12:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Apr 2021 01:49:34 |
| | | |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[AEID](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:07 |
| User entered 'USA-US067-2020-mRNA-1273-P301000015' | System | 25 Nov 2020 12:50:04 |
| User entered 'New' | (b) (4), (b) (6) | 25 Nov 2020 12:50:04 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Skin laceration, LLT: Laceration of head - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 17:57:02 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 17:57:02 |
| Data point term sent to Coder | System | 24 Nov 2020 16:48:11 |
| User entered 'Head Laceration' | Donna Toepfer (b) (4) (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '20 Nov 2020' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'No (N)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 05 Dec 2020 15:39:17 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 06 Dec 2020 17:12:08 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety). | Donna Toepfer (b) (4) | 05 Dec 2020 15:39:26 |
| User entered '30 Nov 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 05 Dec 2020 15:39:17 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 18:04:46 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'I' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '20 Nov 2020' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '22 Nov 2020' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Not Related (NOT RELATED)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Not Related (NOT RELATED)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

None

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered '0' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'I' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered 'I' | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 06 Dec 2020 17:12:19 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety). | Donna Toepfer (b) (4) | 05 Dec 2020 15:39:32 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | Donna Toepfer (b) (4) | 05 Dec 2020 15:39:17 |
| Data Entry Error | (b) (4), (b) (6) | 04 Dec 2020 18:05:22 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | | |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Narrative](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:59 |
| User closed query 'PV Query: Please report if the reason for hospitalization (ie. extensive wound, complications from laceration, etc.).' (Site from Safety). | (b) (4), (b) (6) | 06 Dec 2020 17:12:39 |
| User closed query 'PV Query: Please report the treatment provided for the event.' (Site from Safety). | (b) (4), (b) (6) | 06 Dec 2020 17:12:25 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 06 Dec 2020 17:12:16 |
| Query 'PV Query: Please report if the reason for hospitalization (ie. extensive wound, complications from laceration, etc.).' answered with 'subject had other issues from the attack, he was admitted for evaluation and observation' (Site from Safety). | Donna Toepfer (b) (4) | 05 Dec 2020 15:40:59 |
| Query 'PV Query: Please report the treatment provided for the event.' answered with 'subject received stitches' (Site from Safety). | Donna Toepfer (b) (4) | 05 Dec 2020 15:40:17 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'not available' (Site from Safety). | Donna Toepfer (b) (4) | 05 Dec 2020 15:39:43 |
| User opened query 'PV Query: Please report if the reason for hospitalization (ie. extensive wound, complications from laceration, etc.).' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 18:06:29 |
| User opened query 'PV Query: Please report the treatment provided for the event.' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 18:06:18 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 18:04:58 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 24 Nov 2020 16:50:15 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 24 Nov 2020 16:50:15 |
| User entered 'At safety phone call subject reported that he had been attacked on 11/20/2020. He was admitted to ER with a broken nose and head laceration. He was discharged on 11/22/2020. medical records requested' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 24 Nov 2020 16:50:15 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 24 Nov 2020 16:47:54 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 16:47:54 |

US3242264

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:12:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 24 Nov 2020 16:47:54 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:12:49

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 04:33:25 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 09:10:49 |
| Query 'Per DM CLR: Per Diary Dose 2 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'no med, this could be either med OR interference with activity' (Site from DM). | Donna Toepfer (b) (4) | 01 Feb 2021 13:28:09 |
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 4, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 01 Feb 2021 10:22:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:22 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:27:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:27:48 |
| Data point term sent to Coder | System | 01 Sep 2020 14:26:37 |
| User entered 'Lisinopril' | Donna Toepfer (b) (4) (b) (4) (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Hypertension' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '40' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'mg (mg)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'once daily (QD)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Oral (ORAL)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'UN UNK 2015' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 01 Sep 2020 14:25:47 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

Name of Medication

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:27:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:27:49 |
| Data point term sent to Coder | System | 01 Sep 2020 14:26:37 |
| User entered 'Synthroid' | Donna Toepfer (b) (4) (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Hypothyroidism' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '200' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'ug (ug)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'once daily (QD)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Oral (ORAL)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'UN UNK 2010' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 01 Sep 2020 14:26:20 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:28:55 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:28:55 |
| Data point term sent to Coder | System | 01 Sep 2020 14:27:39 |
| User entered 'Lipitor' | Donna Toepfer (b) (4) (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Hyperlipidemia' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '40' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'mg (mg)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'once daily (QD)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Oral (ORAL)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'UN UNK 2017' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 01 Sep 2020 14:26:48 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

Name of Medication

| Audit | User | Time (GMT) |
|--|---|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:28:54 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Sep 2020 14:28:54 |
| Data point term sent to Coder | System | 01 Sep 2020 14:27:40 |
| User entered 'Ibuprofen' | Donna Toepfer (b) (4) (b) (4) (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Back pain' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '800' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'mg (mg)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'as needed (PRN)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Oral (ORAL)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'UN UNK 1990' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'No (N)' | Donna Toepfer (b) (4) | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Sep 2020 14:27:09 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| 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) | 06 Oct 2020 16:14:11 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Oct 2020 16:14:11 |
| Data point term sent to Coder | System | 06 Oct 2020 16:13:32 |
| User entered 'Influenza Vaccine' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'Flu Prevention' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered '0.5' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered 'mL (mL)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| User entered empty. | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'once (ONCE)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 28 Oct 2020 19:47:49 |
| | | |
| User entered 'other (OTHER)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered empty; reason for change Data Entry Error | Donna Toepfer (b) (4) | 28 Oct 2020 19:47:49 |
| | | |
| User entered 'one time' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered '13 Aug 2020' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered '0' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered '13 Aug 2020' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Nov 2020 05:02:08 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 06 Oct 2020 16:13:30 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User entered empty. | (b) (4), (b) (6) System | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User entered empty. | (b) (4), (b) (6) System | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:11 |
| User entered empty. | (b) (4), (b) (6) System | 06 Oct 2020 16:13:30 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: MUPIROCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Dec 2020 09:57:09 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Dec 2020 09:57:09 |
| Data point term sent to Coder | System | 08 Dec 2020 21:24:13 |
| Coding entries removed. | Donna Toepfer (b) (4) | 08 Dec 2020 21:23:17 |
| User entered 'MUPIROCIN 2%' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 08 Dec 2020 21:23:17 |
| User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: MUPIROCIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 24 Nov 2020 22:19:10 |
| 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 22:19:10 |
| Data point term sent to Coder | System | 24 Nov 2020 21:42:46 |
| User entered 'Mupirocin' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'No (N)' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'Head Laceration' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User closed query 'Per DM CLR: Note, 2% is a concentration, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 11 Dec 2020 09:42:21 |
| Query 'Per DM CLR: Note, 2% is a concentration, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' answered with 'updated' (Site from DM). | Donna Toepfer (b) (4) | 08 Dec 2020 21:23:29 |
| User entered '1' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 08 Dec 2020 21:23:17 |
| User opened query 'Per DM CLR: Note, 2% is a concentration, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 18:30:08 |
| User entered '2.0' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'Other (OTHER)' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'Application' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 08 Dec 2020 21:23:17 |
| User entered 'per cent (%)' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'twice daily (BID)' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered empty. | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'Topical (TOPICAL)' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered empty. | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered '20 Nov 2020' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered '0' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered empty. | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User entered 'No (N)' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 24 Nov 2020 21:42:32 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Dec 2020 01:04:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 18 Dec 2020 01:04:56 |
| Data point term sent to Coder | System | 08 Dec 2020 21:25:13 |
| Coding entries removed. | Donna Toepfer (b) (4) | 08 Dec 2020 21:25:02 |
| | | |
| User entered 'LIDOCAINE OINTMENT 2.5%' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 08 Dec 2020 21:25:02 |
| | | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 02:57:04 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 25 Nov 2020 02:57:04 |
| Data point term sent to Coder | System | 24 Nov 2020 21:43:47 |
| User entered 'Lidocaine Ointment' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:43:26 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'Head Laceration' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User closed query 'Per DM CLR: Note, 2.5% is a concentration/strength, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate..' (Site from DM). | (b) (4), (b) (6) | 11 Dec 2020 09:42:15 |
| Query 'Per DM CLR: Note, 2.5% is a concentration/strength, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate..' ' answered with 'updated' (Site from DM). | Donna Toepfer (b) (4) | 08 Dec 2020 21:25:08 |
| User entered '1' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 08 Dec 2020 21:25:02 |
| User opened query 'Per DM CLR: Note, 2.5% is a concentration/strength, please update medication name to include this concentration and update dose and dose unit with the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate..' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 18:30:53 |
| User entered '2.5' | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:43:26 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'Other (OTHER)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'Application' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 08 Dec 2020 21:25:02 |
| | | |
| User entered 'per cent (%)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'three times daily (TID)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'Topical (TOPICAL)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered '20 Nov 2020' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered '0' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 25 Jan 2021 19:27:18 |
| | | |
| User entered 'Yes (Y)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| User signature succeeded. | (b) (4), (b) (6) Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 27 Jan 2021 21:19:35 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM). | Donna Toepfer (b) (4) | 25 Jan 2021 19:27:37 |
| User entered '30 Nov 2020' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 25 Jan 2021 19:27:18 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 25 Jan 2021 02:07:15 |
| User entered empty. | Erynn McKinley (b) (4) (b) (4) | 24 Nov 2020 21:43:26 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:41:33 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 24 Nov 2020 21:43:26 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| User entered '3' | (b) (4), (b) (6) System | 24 Nov 2020 21:43:26 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| User entered '1' | (b) (4), (b) (6) System | 24 Nov 2020 21:43:26 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:19 |
| User entered '804 (804)' | (b) (4), (b) (6) System | 24 Nov 2020 21:43:26 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

Name of Medication

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTS SYNONYM: JUVEDERM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 19:51:43 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Mar 2021 19:51:43 |
| Data point term sent to Coder | System | 03 Mar 2021 19:51:05 |
| User entered 'Juvederm' | Erynn McKinley (b) (4) (b) (4) | 03 Mar 2021 19:50:55 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'Cosmetic' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'I' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'mL (mL)' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'once (ONCE)' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered empty. | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'UN UNK 2019' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered '0' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'UN UNK 2019' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| | (b) (4), (b) (6) | |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| | | |
| User entered 'No (N)' | Erynn McKinley (b) (4) | 03 Mar 2021 19:50:55 |
| | (b) (4) | |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| User entered empty. | (b) (4), (b) (6) System | 03 Mar 2021 19:50:55 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| User entered empty. | (b) (4), (b) (6) System | 03 Mar 2021 19:50:55 |

US3242264

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:12:49

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 23 Apr 2021 17:32:26 |
| User entered empty. | (b) (4), (b) (6) System | 03 Mar 2021 19:50:55 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:12:49

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 04:33:25 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:46 |
| User entered 'Yes (Y)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:48:05 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:49

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:54 |
| User entered '20 Nov 2020' | Donna Toepfer (b) (4) | 24 Nov 2020 16:48:24 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:49

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 25 Mar 2021 18:15:56 |
| User closed query 'Per DM CLR: Please review if this was done for AE# 4 HEAD LACERATION. If so, please reconcile event terms so there is an appropriate match. Else, note that there is no AE condition that matches this procedure within this timeframe. Review and update necessary ecrfs as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 23 Mar 2021 12:13:40 |
| Query 'Per DM CLR: Please review if this was done for AE# 4 HEAD LACERATION. If so, please reconcile event terms so there is an appropriate match. Else, note that there is no AE condition that matches this procedure within this timeframe. Review and update necessary ecrfs as appropriate. ' answered with 'updated' (Site from DM). | Donna Toepfer (b) (4) | 22 Mar 2021 15:27:10 |
| Signature has been broken. | Donna Toepfer (b) (4) | 22 Mar 2021 15:26:56 |
| User entered 'SUTURES,HeadD' reason for change: Data Entry Error | Donna Toepfer (b) (4) | 22 Mar 2021 15:26:56 |
| User opened query 'Per DM CLR: Please review if this was done for AE# 4 HEAD LACERATION. If so, please reconcile event terms so there is an appropriate match. Else, note that there is no AE condition that matches this procedure within this timeframe. Review and update necessary ecrfs as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 19 Mar 2021 10:50:38 |
| User signature succeeded. | Nathan Segall (b) (4) | 06 Mar 2021 14:45:18 |
| User closed query 'Per DM CLR: Please update to include the location of SUTURES. Update Concomitant Procedure eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) (b) (4), (b) (6) | 05 Mar 2021 09:11:16 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:49

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Query 'Per DM CLR: Please update to include the location of SUTURES. Update Concomitant Procedure eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). DataPoint Un-verified. | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 04 Mar 2021 13:37:37 |
| | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 04 Mar 2021 13:37:18 |
| Signature has been broken. | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 04 Mar 2021 13:37:18 |
| User entered 'SUTURES,HAND' reason for change: Data Entry Error | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 04 Mar 2021 13:37:18 |
| User opened query 'Per DM CLR: Please update to include the location of SUTURES. Update Concomitant Procedure eCRF as appropriate. ' (Site from DM). User signature succeeded. | (b) (4), (b) (6) [REDACTED] | 04 Mar 2021 10:39:22 |
| | Nathan Segall (b) (4) [REDACTED] [REDACTED] | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) [REDACTED] | 28 Jan 2021 19:43:54 |
| User entered 'Sutures' | Donna Toepfer (b) (4) [REDACTED] [REDACTED] | 24 Nov 2020 16:48:24 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:54 |
| User entered 'Adverse Event (AE)' | Donna Toepfer (b) (4) | 24 Nov 2020 16:48:24 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:12:49

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:54 |
| User entered empty. | Donna Toepfer (b) (4) | 24 Nov 2020 16:48:24 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:49

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:14:26 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:54 |
| User entered '24 Nov 2020' | Donna Toepfer (b) (4) | 05 Dec 2020 15:41:50 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:49

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:14:26 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:54 |
| User entered 'Nasal reduction' | Donna Toepfer (b) (4) | 05 Dec 2020 15:41:50 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:49

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:14:26 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:54 |
| User entered 'Adverse Event (AE)' | Donna Toepfer (b) (4) | 05 Dec 2020 15:41:50 |

US3242264

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:12:49

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:14:26 |
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:43:54 |
| User entered empty. | Donna Toepfer (b) (4) | 05 Dec 2020 15:41:50 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[SAEID](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'USA-US067-2020-MRNA-1273-P301000015' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

Death

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Dec 2020 17:12:51 |
| User entered 'US' | System | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | (b) (4) | |
| User entered '2' | System | 06 Dec 2020 17:13:04 |
| User entered '1' | System | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[SAEID](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'USA-US067-2020-MRNA-1273-P301000015' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

Death

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Dec 2020 17:12:51 |
| User entered 'US' | System | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | (b) (4) | |
| User entered '2' | System | 06 Dec 2020 17:13:04 |
| User entered '1' | System | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:12:49

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| User entered '25/Nov/2020 12:50' | System | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:12:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Dec 2020 17:12:51 |
| User entered 'I' | (b) (4), (b) (6) | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[SAEID](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'USA-US067-2020-MRNA-1273-P301000015' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Serious](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

Death

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'Yes (Y)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Nov 2020 12:50:33 |
| User entered 'No (N)' | System | 25 Nov 2020 12:50:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Dec 2020 17:12:51 |
| User entered 'US' | System | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 09 Jun 2021 16:12:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) | 12 Feb 2021 18:20:56 |
| | (b) (4) | |
| User entered '2' | System | 06 Dec 2020 17:13:04 |
| User entered '1' | System | 25 Nov 2020 12:50:44 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:12:49

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| User entered '06/Dec/2020 12:13' | System | 06 Dec 2020 17:13:04 |

US3242264

Folder: SAE USA-US067-2020-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:12:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Nathan Segall (b) (4) (b) (4) | 12 Feb 2021 18:20:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 28 Jan 2021 19:40:46 |
| User entered 'I' | (b) (4), (b) (6) | 06 Dec 2020 17:13:04 |