

US3092021 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:03:00

All time stamps listed in this document are displayed in GMT

US3092021

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 00:22:04

Generated On: 09 Jun 2021 15:03:00

Participant ID

US3092021

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

US3092021

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 05 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

US3092021

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1955 |
| Age | 65 |
| Age Units | YEARS |
| Age (Derived) | 65 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | False |
| Black | True |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

US3092021

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Date of Informed Consent (*dd MMM yyyy*) 5 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

| | |
|-------------|----------------------------------|
| Amendment 1 | <input checked="" type="radio"/> |
| Amendment 2 | <input type="radio"/> |
| Amendment 3 | <input type="radio"/> |
| Amendment 4 | <input type="radio"/> |
| Amendment 5 | <input type="radio"/> |

Was participant enrolled in the study?

| | |
|-----|----------------------------------|
| Yes | <input checked="" type="radio"/> |
| No | <input type="radio"/> |

If No, indicate reason for screen fail

| | |
|---------------------|-----------------------|
| Withdrew Consent | <input type="radio"/> |
| Inclusion/Exclusion | <input type="radio"/> |
| Cohort Full | <input type="radio"/> |
| Other | <input type="radio"/> |

If reason for screen fail is Other, specify _____

Was this participant screened previously?

| | |
|-----|----------------------------------|
| Yes | <input type="radio"/> |
| No | <input checked="" type="radio"/> |

If Yes, previous participant number _____

Enrollment Trigger 1

US3092021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Were any significant conditions reported?

Yes ☒

No ☐

US3092021

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | DIABETES TYPE 2 |
| Start date (dd MMM yyyy) | UN UNK 2002 |
| 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 2002 |
| Start Year (derived) | 2002 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 2011 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2011 |
| Start Year (derived) | 2011 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | HYPERCHOLESTEROLEMIA |
| 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 (4)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | GASTROESOPHAGEAL REFLUX DISEASE |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| 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 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | NEUROPATHY LEGS AND HANDS |
| Start date (dd MMM yyyy) | UN UNK 2013 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2013 |
| Start Year (derived) | 2013 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | LEFT KNEE ARTHROPLASTY |
| Start date (dd MMM yyyy) | UN UNK 2011 |
| 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 2011 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2011 |
| Start Year (derived) | 2011 |
| Stop Month and Year (derived) | JAN 2011 |
| Stop Year (derived) | 2011 |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | OSTEOARTHRITIS ARTHRITIS IN BACK |
| Start date (dd MMM yyyy) | UN UNK 2011 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2011 |
| Start Year (derived) | 2011 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| Condition | LEFT KNEE PAIN |
| Start date (dd MMM yyyy) | UN UNK 2011 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2011 |
| Start Year (derived) | 2011 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3092021

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 05 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:20 (24 HR) |
| Vital Signs Date and Time (derived) | 05 AUG 2020 12:20 |
| Height (xxx.x) | 187.9 cm |
| Weight (xxx.x) | 132.3 kg |
| BMI (xxx.x) | 37.47195 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) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 AUG 2020

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

US3092021

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:26

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 5 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 184615

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|--|
| 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) | 05 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:20 (24 HR) |
| Vital Signs Date and Time (derived) | 05 AUG 2020 12:20 |
| Temperature (xxx.x) | 36.2 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 85 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 143 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 89 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|--|
| 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) | 5 AUG 2020 |
| Time of assessment (00:00-23:59) | 14:54 (24 HR) |
| Vital Signs Date and Time (derived) | 5 AUG 2020 14:54 |
| Temperature (xxx.x) | 96.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 151 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 103 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

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.

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

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) 5 AUG 2020

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

Treatment Date and Time (derived) 5 AUG 2020 13:23

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) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 5 AUG 2020 |
| Collection time (00:00-23:59) | 13:20 (24 HR) |
| Collection date and time (derived) | 5 AUG 2020 13:20 |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 5 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 13:16 | 5 AUG 2020 13:16 |
| Nasopharyngeal Swab 2 | No | | |

US3092021

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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 AUG 2020 14:56

PC Open Date & Time

05 AUG 2020 13:43

PC Close Date & Time

05 AUG 2020 16:13

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 05 AUG 2020 17:08

PC Close Date & Time 06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

98.5 °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

06 AUG 2020 23:28

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 00:02

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 23:49

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

98.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 AUG 2020 00:01

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 AUG 2020 23:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

12 AUG 2020 00:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

05 AUG 2020 14:57

PC Open Date & Time

05 AUG 2020 13:43

PC Close Date & Time

05 AUG 2020 16:13

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 AUG 2020 17:08

PC Close Date & Time

06 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

06 AUG 2020 23:29

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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

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

Yes ☐

No ☒

Please record - **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 AUG 2020 00:03

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

08 AUG 2020 23:50

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

10 AUG 2020 00:01

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

10 AUG 2020 23:42

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

12 AUG 2020 00:02

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 05 AUG 2020 14:57 |
| PC Open Date & Time | 05 AUG 2020 13:43 |
| PC Close Date & Time | 05 AUG 2020 16:13 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

05 AUG 2020 17:08

PC Close Date & Time

06 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

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 ☒

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 AUG 2020 23:30 |
| PC Open Date & Time | 06 AUG 2020 12:00 |
| PC Close Date & Time | 07 AUG 2020 11:59 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

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)

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

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 ☒

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EAB) (1725)

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US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 AUG 2020 23:51 |
| PC Open Date & Time | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

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 ☒

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 00:02 |
| PC Open Date & Time | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

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
EAB) (1725)

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US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 23:44 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

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 ☒

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp 13 AUG 2020 00:02

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 AUG 2020 00:02

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3092021

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 13 AUG 2020 00:02 |
| PC Open Date & Time | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3092021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 2 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 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|---|
| 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) | 2 SEP 2020 |
| Time of assessment (00:00-23:59) | 14:18 (24 HR) |
| Vital Signs Date and Time (derived) | 2 SEP 2020 14:18 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 77 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 115 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 81 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|--|
| 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) | 2 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:50 (24 HR) |
| Vital Signs Date and Time (derived) | 2 SEP 2020 15:50 |
| Temperature (xxx.x) | 97.3 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) | 117 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 88 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

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) 2 SEP 2020

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

Treatment Date and Time (derived) 2 SEP 2020 15:13

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

US3092021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 2 SEP 2020 |
| Collection time (00:00-23:59) | 15:04 (24 HR) |
| Collection date and time (derived) | 2 SEP 2020 15:04 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 02 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 14:58 | 02 SEP 2020 14:58 |
| Nasopharyngeal Swab 2 | No | | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

02 SEP 2020 15:52

PC Open Date & Time

02 SEP 2020 15:33

PC Close Date & Time

02 SEP 2020 18:03

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 02 SEP 2020 23:25 |
| PC Open Date & Time | 02 SEP 2020 18:58 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 23:48

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 00:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 01:30

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 03:23

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 22:17

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:27

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

02 SEP 2020 15:51

PC Open Date & Time

02 SEP 2020 15:33

PC Close Date & Time

02 SEP 2020 18:03

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

02 SEP 2020 23:26

PC Open Date & Time

02 SEP 2020 18:58

PC Close Date & Time

03 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

03 SEP 2020 23:48

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

05 SEP 2020 00:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

06 SEP 2020 01:31

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

07 SEP 2020 03:24

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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 22:18

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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 22:28

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 02 SEP 2020 15:52 |
| PC Open Date & Time | 02 SEP 2020 15:33 |
| PC Close Date & Time | 02 SEP 2020 18:03 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 02 SEP 2020 23:26 |
| PC Open Date & Time | 02 SEP 2020 18:58 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

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 ☒

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 03 SEP 2020 23:49 |
| PC Open Date & Time | 03 SEP 2020 12:00 |
| PC Close Date & Time | 04 SEP 2020 11:59 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

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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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 00:02 |
| PC Open Date & Time | 04 SEP 2020 12:00 |
| PC Close Date & Time | 05 SEP 2020 11:59 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

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 ☒

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 01:31 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

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 ☒

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 03:24 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

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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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 07 SEP 2020 22:18 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

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)

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US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 22:28 |
| PC Open Date & Time | 08 SEP 2020 12:00 |
| PC Close Date & Time | 09 SEP 2020 11:59 |

US3092021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted? Yes ☐
No ☒

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

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

Comments

If Contact Not Made, please provide Comments _____

US3092021

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted? Yes ☐
No ☒

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

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

Comments

If Contact Not Made, please provide Comments _____

US3092021

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 6 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 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 6 OCT 2020 |
| Time of assessment (00:00-23:59) | 14:28 (24 HR) |
| Vital Signs Date and Time (derived) | 6 OCT 2020 14:28 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 104 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3092021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 OCT 2020

Collection time (00:00-23:59)

14:56 (24 HR)

Collection date and time (derived)

6 OCT 2020 14:56

US3092021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:26

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 16:21:09

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 71 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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 <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"/> |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 92 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 NOV 2020 02:29:32 |
| Patient Cloud Open Date & Time | 02 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 06 NOV 2020 23:59 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 99 |
|---|--|
| Have you 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°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="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"/> |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 106 |
|---|--|
| Have you 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 | 18 NOV 2020 22:01:21 |
| Patient Cloud Open Date & Time | 16 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 20 NOV 2020 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 110 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 117 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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 | 28 NOV 2020 06:08:38 |
| Patient Cloud Open Date & Time | 27 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 01 DEC 2020 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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 | 04 DEC 2020 15:59:26 |
| Patient Cloud Open Date & Time | 04 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 08 DEC 2020 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 01:26:52

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

18 DEC 2020 15:34:17

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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 | 26 DEC 2020 17:06:23 |
| Patient Cloud Open Date & Time | 25 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 29 DEC 2020 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| TIMEPOINT | DAY 152 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 JAN 2021 17:55:34 |
| Patient Cloud Open Date & Time | 01 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 05 JAN 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 04:44:14

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 166

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

22 JAN 2021 17:37:12

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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 | 29 JAN 2021 11:44:01 |
| Patient Cloud Open Date & Time | 29 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 02 FEB 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 187 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input 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 | 06 FEB 2021 05:18:11 |
| Patient Cloud Open Date & Time | 05 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 09 FEB 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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 FEB 2021 19:00:48 |
| Patient Cloud Open Date & Time | 12 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 16 FEB 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 19 FEB 2021 00:02:38 |
| Patient Cloud Open Date & Time | 19 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 23 FEB 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

27 FEB 2021 00:17:12

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

05 MAR 2021 01:12:13

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 MAR 2021 00:03:17

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| TIMEPOINT | DAY 229 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 19 MAR 2021 19:09:44 |
| Patient Cloud Open Date & Time | 19 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 23 MAR 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| TIMEPOINT | DAY 236 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 28 MAR 2021 23:57:28 |
| Patient Cloud Open Date & Time | 26 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 30 MAR 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

03 APR 2021 22:26:11

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 11:18:44

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| TIMEPOINT | DAY 257 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 16 APR 2021 22:23:31 |
| Patient Cloud Open Date & Time | 16 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 20 APR 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 15:19:23

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 01:53:57

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| TIMEPOINT | DAY 306 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 18 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 22 JUN 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 20 AUG 2021 00:01 |
|--|-------------------|

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 31 AUG 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 21 SEP 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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="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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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°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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 19 NOV 2021 00:01 |
|--|-------------------|

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 17 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 21 DEC 2021 23:59 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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 <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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐
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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

| 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"/> |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 12 AUG 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 16 AUG 2022 23:59 |
|---|-------------------|

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 26 AUG 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 30 AUG 2022 23:59 |
|---|-------------------|

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐
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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3092021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:03:00

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 03 MAR 2021 09:02:47 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 25 FEB 2021 |
|--------------------------|-------------|

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

| | |
|------------|--------|
| Folder OID | VISIT4 |
|------------|--------|

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 16:31:14

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 25 FEB 2021 |
| Time of assessment (00:00-23:59) | 13:10 (24 HR) |
| Vital Signs Date and Time (derived) | 25 FEB 2021 13:10 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 78 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 129 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 16:31:13

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3092021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 25 FEB 2021 |
| Collection time (00:00-23:59) | 13:48 (24 HR) |
| Collection date and time (derived) | 25 FEB 2021 13:48 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 31 Mar 2021 16:31:13

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 16:31:13

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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 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"/> |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

| | |
|---------------|--|
| O2 Saturation | |
|---------------|--|

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

| | |
|-------------|--|
| Temperature | |
|-------------|--|

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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 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"/> |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

| | |
|---------------|--|
| O2 Saturation | |
|---------------|--|

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

| | |
|-------------|--|
| Temperature | |
|-------------|--|

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

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

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

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

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | No | |
| Day 5 | No | |
| Day 7 | No | |
| Day 9 | No | |
| Day 14 | No | |
| Day 21 | No | |
| Day 28 | No | |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

Visit date (dd MMM yyyy)

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

| | |
|------------|---------|
| Folder OID | SICKD28 |
|------------|---------|

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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.

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3092021

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 28 JAN 2021 |
|--------------------------|-------------|

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

| | |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3092021

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 28 JAN 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>) | 28 JAN 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 |

US3092021

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------|-----------|
| Height | 187.96 cm |
| Weight | 289.8 lb |
| BMI (xxx.x) | 37.28592 |

US3092021

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|--|
| Height | 187.96 cm |
| Weight | 289.8 lb |
| BMI (xxx.x) | 37.28592 |
| 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 JAN 2021 |
| Time of assessment (00:00-23:59) | 13:35 (24 HR) |
| Vital Signs Date and Time (derived) | 28 JAN 2021 13:35 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 78 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 139 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 89 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|--|
| Height | 187.96 cm |
| Weight | 289.8 lb |
| BMI (xxx.x) | 37.28592 |
| 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) | 28 JAN 2021 |
| Time of assessment (00:00-23:59) | 14:40 (24 HR) |
| Vital Signs Date and Time (derived) | 28 JAN 2021 14:40 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify _____ | |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 131 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 81 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3092021

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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) 28 JAN 2021

What was the treatment time? (00:00-23:59) 14:08 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 14:08

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

What was the frequency of the study treatment dosing? ONCE

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

US3092021

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 JAN 2021 |
| Collection time (00:00-23:59) | 14:05 (24 HR) |
| Collection date and time (derived) | 28 JAN 2021 14:05 |

US3092021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 28 JAN 2021 |
| Collection time (00:00 - 23:59) | 14:02 |
| Collection Date and Time (derived) | 28 JAN 2021 14:02 |

US3092021

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

| | |
|--|--------------------------------------|
| Is the participant continuing to the next visit? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Continuing Flag | 1 |
| OLD29 Placebo Flag | 1 |

US3092021

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 25 FEB 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 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|---|
| 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) | 25 FEB 2021 |
| Time of assessment (00:00-23:59) | 13:10 (24 HR) |
| Vital Signs Date and Time (derived) | 25 FEB 2021 13:10 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 78 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 129 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 73 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

| | |
|-------------------------------------|--|
| 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) | 25 FEB 2021 |
| Time of assessment (00:00-23:59) | 14:24 (24 HR) |
| Vital Signs Date and Time (derived) | 25 FEB 2021 14:24 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 78 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 132 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3092021

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3092021

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

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) 25 FEB 2021

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 13:52

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

US3092021

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:17:14

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3092021

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092021

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Mar 2021 00:59:32

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 26 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 | OLD57 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Mar 2021 00:59:32

Generated On: 09 Jun 2021 15:03:00

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 26 MAR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 13:25 (24 HR) |
| Vital Signs Date and Time (derived) | 26 MAR 2021 13:25 |
| Temperature (<i>xxx.x</i>) | 98.2 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 140 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 95 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3092021

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Mar 2021 00:59:32

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3092021

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Mar 2021 00:59:32

Generated On: 09 Jun 2021 15:03:00

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 26 MAR 2021 |
| Collection time (00:00-23:59) | 13:57 (24 HR) |
| Collection date and time (derived) | 26 MAR 2021 13:57 |

US3092021

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|--|--|
| AEID | USA-US086-2021-MRNA-1273-P30 1000002 |
| Adverse event | COPD EXACEBRATION |
| 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) | 15 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) | 17 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) | 15 NOV 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 17 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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US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|--|---|
| 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 | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | SUBJECT WAS HOSPITALIZED PER DIAGNOSED WITH COPD EXACERBATION OUTBREAK. |
| Serious Adverse Event Derived (CSA Programming Field Only) | 1 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | 0 |

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EAB) (1725)

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US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

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

Yes ☒

No ☐

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

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 100

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

| | | |
|--|--------------------------|----------------------------------|
| | 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 2008 | |
| 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"/> |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

Name of Medication TRESIBA

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 200

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

If dose unit is Other, specify UNITS

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 (2)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

| | | |
|--|--------------------------|----------------------------------|
| | 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) _____ | | |
| Start date completely unknown | | True |
| 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"/> |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

| | | |
|--|--------------------------|----------------------------------|
| | 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) _____ | | |
| Start date completely unknown | | True |
| 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) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

Name of Medication OMEPROZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL RELUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

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

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTERLEMIA

Dose per administration 80

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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US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

| | | |
|--|--------------------------|----------------------------------|
| | 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) _____ | | |
| Start date completely unknown | | True |
| 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"/> |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

Name of Medication HYDROCODNE
(VICODEN)/TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE PAIN

Dose per administration 10-325

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2281

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 00:23:24

Generated On: 09 Jun 2021 15:03:00

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN UNK 2011 | |
| 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"/> |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 02:21:53

Generated On: 09 Jun 2021 15:03:00

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|------------|---------------------------------|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

US3092021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 19 Feb 2021 00:23:25

Generated On: 09 Jun 2021 15:03:00

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 ☐

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|--|--|
| SAEID | USA-US086-2021-MRNA-1273-P301000002 |
| 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 | VALENTINE |
| Investigator's Last Name | EBUH |
| Site Address: Street | 2701 S HAMPTON ROAD, SUITE 250 |
| Site Address: City | DALLAS |
| Site Address: State | TX |
| Site Address: Postal Code | 75033 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| SAEID | USA-US086-2021-MRNA-1273-P301000002 |
| 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 | VALENTINE |
| Investigator's Last Name | EBUH |
| Site Address: Street | 2701 S HAMPTON ROAD, SUITE 250 |
| Site Address: City | DALLAS |
| Site Address: State | TX |
| Site Address: Postal Code | 75033 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 07/JAN/2021 12:32 |
| 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 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| SAEID | USA-US086-2021-MRNA-1273-P301000002 |
| 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 | VALENTINE |
| Investigator's Last Name | EBUH |
| Site Address: Street | 2701 S HAMPTON ROAD, SUITE 250 |
| Site Address: City | DALLAS |
| Site Address: State | TX |
| Site Address: Postal Code | 75033 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 05/FEB/2021 17:39 |
| 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 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Mar 2021 22:38:13

Generated On: 09 Jun 2021 15:03:00

| | |
|---|--|
| SAEID | USA-US086-2021-MRNA-1273-P301000002 |
| 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 | VALENTINE |
| Investigator's Last Name | EBUH |
| Site Address: Street | 2701 S HAMPTON ROAD, SUITE 250 |
| Site Address: City | DALLAS |
| Site Address: State | TX |
| Site Address: Postal Code | 75033 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 3 |
| Date of submission (Pre-filled from custom function) | 11/MAR/2021 07:09 |
| 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

US3092021 (Prod: Global Medical Research - M3 Wake Research)

US3092021

Form: Participant Creation

Generated On: 09 Jun 2021 15:03:00

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 16:13:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:22:04 |
| User entered 'US3092021' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 05 Aug 2020 18:14:17 |

US3092021

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:31 |

US3092021

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '05 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 05 Aug 2020 18:14:18 |

US3092021

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Clinic (Clinic)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:31 |

US3092021

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'SCRN' | System | 05 Aug 2020 18:14:31 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered (b) (6) 1955' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 05 Aug 2020 18:14:19 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '65' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'YEARS' | System | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '65' | System | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Sex](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Male (M)' reason for change: Data Entry Error | (b) (4) | |
| | Shraddha Dubal (b) (4) | 18 Aug 2020 18:31:50 |
| User entered 'Female (F)' | (b) (4) | |
| | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

White

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:32:24 |
| User entered '1' | (b) (4) Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Black](#)

| Audit | User | Time (GMT) |
|--|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '1' reason for change: Data Entry Error | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:31:50 |
| User entered '0' | (b) (4) Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:03:00

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:14:57 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

[Date of Informed Consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '5 Aug 2020' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Aug 2020' | System | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2020' | System | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Amendment 1 (1)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:10 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 05 Aug 2020 18:14:18 |

US3092021

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:03:00

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'I' | System | 05 Aug 2020 18:15:16 |

US3092021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:16 |

US3092021

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:03:00

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Robert Miranda (b) (4) | 10 Aug 2020 13:29:22 |
| User entered 'No (N)' reason for change: Data Entry Error | Robert Miranda (b) (4) | 10 Aug 2020 13:29:10 |
| User entered 'Yes (Y)' | Robert Miranda (b) (4) | 10 Aug 2020 13:28:55 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 18 Aug 2020 21:47:38 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 21:47:38 |
| Data point term sent to Coder | System | 18 Aug 2020 18:23:50 |
| User entered 'Diabetes Type 2' | Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2002' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2002' | System | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2002' | System | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:23:34 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 21:47:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 21:47:46 |
| Data point term sent to Coder | System | 18 Aug 2020 18:24:51 |
| User entered 'Hypertension' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2011' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2011' | System | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2011' | System | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:23:56 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 18 Aug 2020 21:47:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 21:47:46 |
| Data point term sent to Coder | System | 18 Aug 2020 18:24:56 |
| User entered 'Hypercholesterolemia' | Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2015' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2015' | System | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2015' | System | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:24:37 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 21:56:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 21:56:24 |
| Data point term sent to Coder | System | 18 Aug 2020 18:25:57 |
| User entered 'Gastroesophageal Reflux Disease' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2005' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2005' | System | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2005' | System | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:25:22 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy peripheral - version MedDRA\23.0. | Coder Import (b) (4) | 23 Nov 2020 09:55:15 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 23 Nov 2020 09:55:15 |
| User closed query 'Per CDM, per DM CLR re-query: Response noted; however, please, at the next patient contact, provide the specific body location of NEUROPATHY. Review and update as appropriate, else clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 12:05:35 |
| Query 'Per CDM, per DM CLR re-query: Response noted; however, please, at the next patient contact, provide the specific body location of NEUROPATHY. Review and update as appropriate, else clarify. Thank you. ' answered with 'Completed' (Site from DM). | Catina Adams (b) (4) | 23 Oct 2020 16:37:15 |
| Data point term sent to Coder | System | 23 Oct 2020 16:37:03 |
| Coding entries removed. | Catina Adams (b) (4) | 23 Oct 2020 16:37:01 |
| User entered 'NEUROPATHY Legs and hands' reason for change: Data Entry Error | Catina Adams (b) (4) | 23 Oct 2020 16:37:01 |
| User opened query 'Per CDM, per DM CLR re-query: Response noted; however, please, at the next patient contact, provide the specific body location of NEUROPATHY. Review and update as appropriate, else clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 08:23:42 |
| User closed query 'Per DM CLR: Please review and reflect the type and specific body location of NEUROPATHY. Update Med History eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 08:02:06 |
| Query 'Per DM CLR: Please review and reflect the type and specific body location of NEUROPATHY. Update Med History eCRF as appropriate. ' answered with 'location not specified ' (Site from DM). | destiny robinson (b) (4) | 19 Oct 2020 18:33:47 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User opened query 'Per DM CLR: Please review and reflect the type and specific body location of NEUROPATHY. Update Med History eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 31 Aug 2020 00:56:04 |
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 22:01:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 22:01:01 |
| Data point term sent to Coder | System | 18 Aug 2020 18:27:00 |
| User entered 'Neuropathy' | Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2013' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2013' | System | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2013' | System | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:26:09 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 10:37:32 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'Arthritis is listed' (Site from DM). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 20:24:29 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 31 Aug 2020 00:56:15 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee arthroplasty - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 23:32:47 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 18 Aug 2020 23:32:47 |
| Data point term sent to Coder | System | 18 Aug 2020 18:27:06 |
| User entered 'Left Knee Arthroplasty' | Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2011' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | 18 Aug 2020 18:27:31 |
| User entered 'Yes (Y)' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:26:54 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2011' reason for change: | (b) (4) | |
| Data Entry Error | Shraddha Dubal (b) (4) | 18 Aug 2020 18:27:31 |
| User entered empty. | (b) (4) | |
| | Shraddha Dubal (b) (4) | 18 Aug 2020 18:26:54 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2011' | System | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2011' | System | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2011' | System | 18 Aug 2020 18:27:31 |
| User entered empty. | System | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2011' | System | 18 Aug 2020 18:27:31 |
| User entered empty. | System | 18 Aug 2020 18:26:54 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 08:50:30 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis spinal - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 06 Feb 2021 00:54:52 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 06 Feb 2021 00:54:52 |
| Data point term sent to Coder | System | 06 Feb 2021 00:53:30 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM). | Heather Jimenez (b) (4) (b) (4) | 06 Feb 2021 00:52:41 |
| Coding entries removed. | Heather Jimenez (b) (4) (b) (4) | 06 Feb 2021 00:52:34 |
| User entered 'Osteoarthritis ARTHRITIS IN BACK' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 06 Feb 2021 00:52:34 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 03:24:34 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' canceled (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 03:24:29 |

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 02:51:20 |
| User closed query 'Per CDM, per DM CLR re-query: Response noted; however, please, at the next patient contact, provide the type and specific body location of ARTHRITIS. Review and update as appropriate, else clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 12:06:00 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Spondyloarthropathies, PT: Spondylitis, LLT: Back arthritis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Oct 2020 16:43:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 23 Oct 2020 16:43:28 |
| Data point term sent to Coder | System | 23 Oct 2020 16:42:14 |
| Query 'Per CDM, per DM CLR re-query: Response noted; however, please, at the next patient contact, provide the type and specific body location of ARTHRITIS. Review and update as appropriate, else clarify. Thank you. ' answered with 'Corrected' (Site from DM). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:41:47 |
| Coding entries removed. | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:41:35 |
| User entered 'ARTHRITIS in Back' reason for change: Data Entry Error | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:41:35 |
| User opened query 'Per CDM, per DM CLR re-query: Response noted; however, please, at the next patient contact, provide the type and specific body location of ARTHRITIS. Review and update as appropriate, else clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 08:24:43 |
| User closed query 'Per DM CLR: Please review and reflect the type and specific body location of ARTHRITIS. Update Med History eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 08:24:43 |
| Query 'Per DM CLR: Please review and reflect the type and specific body location of ARTHRITIS. Update Med History eCRF as appropriate. ' answered with 'not specified ' (Site from DM). | destiny robinson (b) (4) (b) (4) | 19 Oct 2020 18:34:23 |

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User opened query 'Per DM CLR: Please review and reflect the type and specific body location of ARTHRITIS. Update Med History eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 31 Aug 2020 00:56:26 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 22:06:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 22:06:16 |
| Data point term sent to Coder | System | 18 Aug 2020 18:28:10 |
| User entered 'Arthritis' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2011' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2011' | System | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2011' | System | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:28:01 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per CDM, per DM CLR re-query: Response noted; however, please confirm in a query response that no medication is taken by the patient to treat this condition, else add a Con Med, if applicable. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Nov 2020 12:06:18 |
| Query 'Per CDM, per DM CLR re-query: Response noted; however, please confirm in a query response that no medication is taken by the patient to treat this condition, else add a Con Med, if applicable. Thank you.' answered with 'Not taking meds currently.' (Site from DM). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:42:21 |
| User opened query 'Per CDM, per DM CLR re-query: Response noted; however, please confirm in a query response that no medication is taken by the patient to treat this condition, else add a Con Med, if applicable. Thank you.' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 08:26:38 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 08:26:38 |
| Query 'Per DM CLR: Please note that there is no Con destiny robinson Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'no medication listed' (Site from DM). | (b) (4) (b) (4) | 19 Oct 2020 18:35:14 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM). | (b) (4), (b) (6) | 31 Aug 2020 00:56:36 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

[Condition](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 22:11:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 18 Aug 2020 22:11:46 |
| Data point term sent to Coder | System | 18 Aug 2020 18:29:13 |
| User entered 'COPD' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:20 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'UN UNK 2018' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:28:20 |

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2018' | System | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2018' | System | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 18 Aug 2020 18:28:20 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

Condition

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Feb 2021 15:49:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 10 Feb 2021 15:49:48 |
| Data point term sent to Coder | System | 10 Feb 2021 15:49:02 |
| User entered 'LEFT KNEE PAIN' | destiny robinson (b) (4) | 10 Feb 2021 15:48:36 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'un UNK 2011' | (b) (4) destiny robinson (b) (4) (b) (4) | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) destiny robinson (b) (4) (b) (4) | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) destiny robinson (b) (4) | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) destiny robinson (b) (4) (b) (4) | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | (b) (4) destiny robinson (b) (4) (b) (4) | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'Jan 2011' | System | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '2011' | System | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered empty. | System | 10 Feb 2021 15:48:36 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '05 Aug 2020' | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '12:20' | (b) (4) Shraddha Dubal (b) (4) (b) (4) | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered '05 Aug 2020 12:20' | System | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '187.9' cm | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |
| DataPoint set to visible. | (b) (4) System | 05 Aug 2020 18:15:16 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '132.3' kg | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |
| DataPoint set to visible. | (b) (4) System | 05 Aug 2020 18:15:16 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| Amendment Manager: User entered '37.47195' | System | 16 Sep 2020 23:44:21 |
| User entered '37.5' | System | 18 Aug 2020 18:29:35 |
| DataPoint set to visible. | System | 05 Aug 2020 18:15:16 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'kg/m2' | System | 18 Aug 2020 18:29:35 |
| DataPoint set to visible. | System | 05 Aug 2020 18:15:16 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:37:35 |
| User entered '36.2' C | Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 20:37:35 |
| User entered 'Oral (Oral)' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:37:35 |
| User entered '85' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'bpm' | System | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:37:35 |
| User entered '20' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'breaths/min' | System | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:37:35 |
| User entered '143' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'mmHg' | System | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:37:35 |
| User entered '89' | Shraddha Dubal (b) (4) | 18 Aug 2020 18:29:35 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User entered 'mmHg' | System | 18 Aug 2020 18:29:35 |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| | | |

US3092021

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| | | |

US3092021

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 17 Aug 2020 18:42:30 |

US3092021

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Sep 2020 10:43:12 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 02 Sep 2020 20:43:16 |
| User entered '5 Aug 2020' | Vicki Martinez (b) (4) (b) (4) | 17 Aug 2020 18:42:30 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

[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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

[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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Sep 2020 20:28:21 |
| User entered 'No (N)' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 20:28:21 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 05 Aug 2020 18:15:45 |
| | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |
| | (b) (4) | |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'I' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

Other

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:03:00

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 07:52:51 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 05 Aug 2020 18:15:45 |

US3092021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:26:37 |

US3092021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '5 Aug 2020' | Vicki Martinez (b) (4) | 05 Aug 2020 18:26:37 |

US3092021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[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 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Clinic (Clinic)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:26:37 |

US3092021

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'VISIT1' | System | 05 Aug 2020 18:26:37 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '05 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 05 Aug 2020 18:14:32 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | 21 Aug 2020 02:18:20 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 02:18:19 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 05 Aug 2020 18:14:32 |
| User entered '184615' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 05 Aug 2020 18:14:32 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 05 Aug 2020 18:14:32 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

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 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:27:33 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

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 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:27:33 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:27:33 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:27:33 |

US3092021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:03:00

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:27:33 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

Height

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Heather Jimenez (b) (4) | 22 Sep 2020 20:38:07 |
| User entered '187.9' cm | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

[Weight](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Heather Jimenez (b) (4) | 22 Sep 2020 20:38:07 |
| User entered '132.3' kg | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

Height

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Heather Jimenez (b) (4) | 22 Sep 2020 20:38:07 |
| User entered '187.9' cm | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

[Weight](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Heather Jimenez (b) (4) | 22 Sep 2020 20:38:07 |
| User entered '132.3' kg | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '05 Aug 2020' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '12:20' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered '05 Aug 2020 12:20' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '36.2' C | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (Oral)' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '85' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'bpm' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '20' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'breaths/min' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '143' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '89' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

Height

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Heather Jimenez (b) (4) | 22 Sep 2020 20:38:07 |
| User entered '187.9' cm | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

[Weight](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Heather Jimenez (b) (4) | 22 Sep 2020 20:38:07 |
| User entered '132.3' kg | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | |
| User entered '5 Aug 2020' reason for change: Data Entry Error | System | 17 Aug 2020 18:43:06 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | Vicki Martinez (b) (4) | 17 Aug 2020 18:43:06 |
| User entered '05 2020' (non-conformant). | (b) (4) | |
| | System | 10 Aug 2020 13:45:05 |
| | Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:54' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered '5 Aug 2020 14:54' | System | 17 Aug 2020 18:43:06 |
| User entered '05 2020 14:54' (non-conformant). | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| User closed query 'Per CDM: Please verify the Value or the Unit entered, as it is unexpected for Temperature to be this high, and update as appropriate. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 15 Apr 2021 13:27:26 |
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 15 Apr 2021 13:27:00 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Confirmed per source NCS. Not an AE.' (Site from System). | (b) (4), (b) (6) | 14 Apr 2021 17:28:19 |
| Query 'Per CDM: Please verify the Value or the Unit entered, as it is unexpected for Temperature to be this high, and update as appropriate. Thank you.' answered with 'CONFIRMED, DATA CORRECTED' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 19:37:39 |
| User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 12 Apr 2021 19:36:33 |
| Signature has been broken. | (b) (4), (b) (6) | 12 Apr 2021 19:36:33 |
| User entered '96.3' F reason for change: Data Entry Error | | 12 Apr 2021 19:36:33 |
| User opened query 'Per CDM: Please verify the Value or the Unit entered, as it is unexpected for Temperature to be this high, and update as appropriate. Thank you.' (Site from DM). | | 12 Apr 2021 15:10:32 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) (b) (4) | 19 Feb 2021 00:23:27 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4), (b) (6) | 22 Oct 2020 09:44:47 |
| Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'abnormal ncs per PI' (Site from System). | destiny robinson (b) (4) | 21 Oct 2020 19:35:43 |
| User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 21 Oct 2020 19:35:13 |
| Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 21 Oct 2020 19:35:13 |
| User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 21 Oct 2020 19:35:13 |
| User entered '96.3' C reason for change: Data Entry Error | destiny robinson (b) (4) | 21 Oct 2020 19:35:13 |
| Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 16 Sep 2020 23:44:21 |
| User entered '96.3' F | Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (Oral)' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '73' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'bpm' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 21 Oct 2020 19:35:54 |
| User entered '14' reason for change: Data Entry Error | destiny robinson (b) (4) | 21 Oct 2020 19:35:54 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | |
| User entered empty. | System | 10 Aug 2020 13:45:05 |
| | Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'breaths/min' | System | 21 Oct 2020 19:35:54 |
| User entered empty. | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '151' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:45:05 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | (b) (4) | 16 Sep 2020 23:44:20 |
| User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 10 Aug 2020 13:45:05 |
| User entered '103' | Robert Miranda (b) (4) | 10 Aug 2020 13:45:05 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 14:37:16 |
| Data hard unlocked. | | 12 Apr 2021 14:52:55 |
| Data hard locked. | | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 10 Aug 2020 13:45:05 |

US3092021

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | 17 Aug 2020 18:42:55 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 10 Aug 2020 13:47:58 |
| | Robert Miranda (b) (4) | |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Vicki Martinez (b) (4) | 17 Aug 2020 18:42:55 |
| User entered '05 Aug 2020' | Robert Miranda (b) (4) | 10 Aug 2020 13:47:58 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '5 Aug 2020' | Vicki Martinez (b) (4) | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '13:23' | Vicki Martinez (b) (4) | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '5 Aug 2020 13:23' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Left Arm (LEFT ARM)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'ONCE' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'INTRAMUSCULAR' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5AUG2020 is reported under Visit 1 Day 1 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) (4), (b) (6) | 03 Nov 2020 10:56:14 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5AUG2020 is reported under Visit 1 Day 1 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 'Corrected' (Site from DM). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:11:37 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:11:12 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 5AUG2020 is reported under Visit 1 Day 1 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) | 21 Oct 2020 10:28:42 |
| User entered 'No (N)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:49:37 |

US3092021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '5 Aug 2020' reason for change: Data Entry Error | Catina Adams (b) (4) | 23 Oct 2020 16:11:12 |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 13:49:37 |

US3092021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '13:20' reason for change: Data Entry Error | Catina Adams (b) (4) | 23 Oct 2020 16:11:12 |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 13:49:37 |

US3092021

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '5 Aug 2020 13:20' | System | 23 Oct 2020 16:11:12 |
| User entered empty. | System | 10 Aug 2020 13:49:37 |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:00

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System). | (b) (4) | |
| Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System). | System | 22 Sep 2020 20:29:16 |
| User entered '5 Aug 2020' reason for change: Data Entry Error | System | 22 Sep 2020 20:29:16 |
| User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System). | System | 22 Sep 2020 20:29:16 |
| User entered empty. | System | 18 Aug 2020 18:33:35 |
| | Robert Miranda (b) (4) | 10 Aug 2020 13:52:59 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Robert Miranda (b) (4) | 10 Aug 2020 13:52:59 |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Shraddha Dubal (b) (4) | 18 Aug 2020 18:33:35 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 13:52:59 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System). | (b) (4) | 22 Sep 2020 20:29:30 |
| Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System). | System | 22 Sep 2020 20:29:30 |
| User entered '13:16' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 20:29:30 |
| User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System). | (b) (4) | 18 Aug 2020 18:33:35 |
| User entered empty. | System | 18 Aug 2020 18:33:35 |
| | Robert Miranda (b) (4) | 10 Aug 2020 13:52:59 |
| | (b) (4) | |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '5 Aug 2020 13:16' | System | 22 Sep 2020 20:29:30 |
| User entered empty. | System | 10 Aug 2020 13:52:59 |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:52:59 |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 13:52:59 |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 13:52:59 |

US3092021

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered empty. | System | 10 Aug 2020 13:52:59 |

US3092021

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 05 Aug 2020 18:28:22 |

US3092021

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 05 Aug 2020 18:28:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:55:47', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2521e0af-22f1-4263-891a-ea8f95f41559' User entered 'Yes (Y)' | System | 05 Aug 2020 19:56:29 |
| | System | 05 Aug 2020 19:56:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:56:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2521e0af-22f1-4263-891a-ea8f95f41559' User entered '96.3' | System | 05 Aug 2020 19:56:29 |
| | System | 05 Aug 2020 19:56:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:56:18', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2521e0af-22f1-4263-891a-ea8f95f41559' | System | 05 Aug 2020 19:56:29 |
| User entered 'No (N)' | System | 05 Aug 2020 19:56:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:56:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2521e0af-22f1-4263-891a-ea8f95f41559' | System | 05 Aug 2020 19:56:29 |
| User entered '05 Aug 2020 14:56' | System | 05 Aug 2020 19:56:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 13:43' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 16:13' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 17:08' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 2' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:28:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '309444f3-e924-4cf2-8265-e67feeb9d849' | System | 07 Aug 2020 04:28:41 |
| User entered 'Yes (Y)' | System | 07 Aug 2020 04:28:41 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:28:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '309444f3-e924-4cf2-8265-e67feeb9d849' User entered '98.5' | System | 07 Aug 2020 04:28:41 |
| | System | 07 Aug 2020 04:28:41 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:28:31', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '309444f3-e924-4cf2-8265-e67feeb9d849' | System | 07 Aug 2020 04:28:41 |
| User entered 'No (N)' | System | 07 Aug 2020 04:28:41 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:28:39', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '309444f3-e924-4cf2-8265-e67feeb9d849' | System | 07 Aug 2020 04:28:41 |
| User entered '06 Aug 2020 23:28' | System | 07 Aug 2020 04:28:41 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 3' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:01:49', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f487f181-c0d3-426f-9a76-4ab0b344332f' User entered 'Yes (Y)' | System | 08 Aug 2020 05:02:26 |
| | System | 08 Aug 2020 05:02:26 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:01:59', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f487f181-c0d3-426f-9a76-4ab0b344332f' User entered '98.2' | System | 08 Aug 2020 05:02:26 |
| | System | 08 Aug 2020 05:02:26 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:02:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f487f181-c0d3-426f-9a76-4ab0b344332f' | System | 08 Aug 2020 05:02:26 |
| User entered 'No (N)' | System | 08 Aug 2020 05:02:26 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:02:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f487f181-c0d3-426f-9a76-4ab0b344332f' User entered '08 Aug 2020 00:02' | System | 08 Aug 2020 05:02:26 |
| | System | 08 Aug 2020 05:02:26 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 4' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:48:53', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ec57f212-4ec5-47b5-a2d2-8bb7f16cfe99' | System | 09 Aug 2020 04:49:31 |
| User entered 'Yes (Y)' | System | 09 Aug 2020 04:49:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:49:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ec57f212-4ec5-47b5-a2d2-8bb7f16cfe99' | System | 09 Aug 2020 04:49:31 |
| User entered '98.2' | System | 09 Aug 2020 04:49:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:49:16', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ec57f212-4ec5-47b5-a2d2-8bb7f16cfe99' | System | 09 Aug 2020 04:49:31 |
| User entered 'No (N)' | System | 09 Aug 2020 04:49:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:49:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ec57f212-4ec5-47b5-a2d2-8bb7f16cfe99' | System | 09 Aug 2020 04:49:31 |
| User entered '08 Aug 2020 23:49' | System | 09 Aug 2020 04:49:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 5' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:00:06', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '213fd980-c39f-41cb-b67f-837fb056e571' User entered 'Yes (Y)' | System | 10 Aug 2020 05:01:07 |
| | System | 10 Aug 2020 05:01:07 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:00:20', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '213fd980-c39f-41cb-b67f-837fb056e571' User entered '98.2' | System | 10 Aug 2020 05:01:07 |
| | System | 10 Aug 2020 05:01:07 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:00:35', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '213fd980-c39f-41cb-b67f-837fb056e571' | System | 10 Aug 2020 05:01:07 |
| User entered 'Yes (Y)' | System | 10 Aug 2020 05:01:07 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will collect at next contact ' (Site from System). | (b) (4) | 20 Oct 2020 04:51:36 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will collect at next contact ' (Site from System). | destiny robinson (b) (4) | 19 Oct 2020 18:29:55 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 10 Aug 2020 05:01:07 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:00:55', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '213fd980-c39f-41cb-b67f-837fb056e571' | System | 10 Aug 2020 05:01:07 |
| User entered '1' | System | 10 Aug 2020 05:01:07 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:00:55', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '213fd980-c39f-41cb-b67f-837fb056e571' User entered '0' | System | 10 Aug 2020 05:01:07 |
| | System | 10 Aug 2020 05:01:07 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:03', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '213fd980-c39f-41cb-b67f-837fb056e571' | System | 10 Aug 2020 05:01:07 |
| User entered '10 Aug 2020 00:01' | System | 10 Aug 2020 05:01:07 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '10 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 6' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:41:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '67c48233-d95a-4f31-a3f4-073807965017' | System | 11 Aug 2020 04:42:12 |
| User entered 'Yes (Y)' | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:41:49', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '67c48233-d95a-4f31-a3f4-073807965017' User entered '97.8' | System | 11 Aug 2020 04:42:12 |
| | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:41:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '67c48233-d95a-4f31-a3f4-073807965017' | System | 11 Aug 2020 04:42:12 |
| User entered 'Yes (Y)' | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will collect at next contact ' (Site from System). | (b) (4) | 20 Oct 2020 04:51:46 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' | destiny robinson (b) (4) | 19 Oct 2020 18:30:21 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '67c48233-d95a-4f31-a3f4-073807965017' | System | 11 Aug 2020 04:42:12 |
| User entered '1' | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '67c48233-d95a-4f31-a3f4-073807965017' User entered '0' | System | 11 Aug 2020 04:42:12 |
| | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '67c48233-d95a-4f31-a3f4-073807965017' User entered '10 Aug 2020 23:42' | System | 11 Aug 2020 04:42:12 |
| | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '10 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '11 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 7' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:01:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'fc415184-e03d-4f9b-91fe-8c25896aa618' | System | 12 Aug 2020 05:01:58 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 05:01:58 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:01:45', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'fc415184-e03d-4f9b-91fe-8c25896aa618' User entered '97.7' | System | 12 Aug 2020 05:01:58 |
| | System | 12 Aug 2020 05:01:58 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:01:50', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'fc415184-e03d-4f9b-91fe-8c25896aa618' | System | 12 Aug 2020 05:01:58 |
| User entered 'No (N)' | System | 12 Aug 2020 05:01:58 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:01:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'fc415184-e03d-4f9b-91fe-8c25896aa618' | System | 12 Aug 2020 05:01:58 |
| User entered '12 Aug 2020 00:01' | System | 12 Aug 2020 05:01:58 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '11 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '12 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:56:45', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '21fb9f14-8457-4402-8073-5ff26b08cd9d' | System | 05 Aug 2020 19:57:15 |
| User entered 'None (1)' | System | 05 Aug 2020 19:57:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:56:51', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '21fb9f14-8457-4402-8073-5ff26b08cd9d' | System | 05 Aug 2020 19:57:15 |
| User entered 'No (N)' | System | 05 Aug 2020 19:57:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:56:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '21fb9f14-8457-4402-8073-5ff26b08cd9d' User entered 'No (N)' | System | 05 Aug 2020 19:57:15 |
| | System | 05 Aug 2020 19:57:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:02', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '21fb9f14-8457-4402-8073-5ff26b08cd9d' | System | 05 Aug 2020 19:57:15 |
| User entered 'None (1)' | System | 05 Aug 2020 19:57:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:12', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '21fb9f14-8457-4402-8073-5ff26b08cd9d' User entered '05 Aug 2020 14:57' | System | 05 Aug 2020 19:57:15 |
| | System | 05 Aug 2020 19:57:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 13:43' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 16:13' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| | | |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| | | |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 17:08' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 2' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:29:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0c314145-7096-4a81-90b7-e60aaf0df698' | System | 07 Aug 2020 04:29:52 |
| User entered 'Does not interfere with activity (2)' | System | 07 Aug 2020 04:29:52 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:29:21', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0c314145-7096-4a81-90b7-e60aaf0df698' | System | 07 Aug 2020 04:29:52 |
| User entered 'No (N)' | System | 07 Aug 2020 04:29:52 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:29:25', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0c314145-7096-4a81-90b7-e60aaf0df698' | System | 07 Aug 2020 04:29:52 |
| User entered 'No (N)' | System | 07 Aug 2020 04:29:52 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:29:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0c314145-7096-4a81-90b7-e60aaf0df698' | System | 07 Aug 2020 04:29:52 |
| User entered 'Does not interfere with activity (2)' | System | 07 Aug 2020 04:29:52 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:29:50', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0c314145-7096-4a81-90b7-e60aaf0df698' User entered '06 Aug 2020 23:29' | System | 07 Aug 2020 04:29:52 |
| | System | 07 Aug 2020 04:29:52 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 3' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:02:52', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '636cc77b-1f85-4963-a083-afe411eb1ea3' | System | 08 Aug 2020 05:03:42 |
| User entered 'None (1)' | System | 08 Aug 2020 05:03:42 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:03:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '636cc77b-1f85-4963-a083-afe411eb1ea3' | System | 08 Aug 2020 05:03:42 |
| User entered 'Yes (Y)' | System | 08 Aug 2020 05:03:42 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:03:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '636cc77b-1f85-4963-a083-afe411eb1ea3' User entered '1' | System | 08 Aug 2020 05:03:42 |
| | System | 08 Aug 2020 05:03:42 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:03:28', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '636cc77b-1f85-4963-a083-afe411eb1ea3' | System | 08 Aug 2020 05:03:42 |
| User entered 'No (N)' | System | 08 Aug 2020 05:03:42 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:03:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '636cc77b-1f85-4963-a083-afe411eb1ea3' User entered 'None (1)' | System | 08 Aug 2020 05:03:42 |
| | System | 08 Aug 2020 05:03:42 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:03:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '636cc77b-1f85-4963-a083-afe411eb1ea3' User entered '08 Aug 2020 00:03' | System | 08 Aug 2020 05:03:42 |
| | System | 08 Aug 2020 05:03:42 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 4' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:49:35', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '164bbe57-4761-4484-a8c1-8768c885eaf3' | System | 09 Aug 2020 04:50:08 |
| User entered 'None (1)' | System | 09 Aug 2020 04:50:08 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:49:49', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '164bbe57-4761-4484-a8c1-8768c885eaf3' User entered 'No (N)' | System | 09 Aug 2020 04:50:08 |
| | System | 09 Aug 2020 04:50:08 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:49:54', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '164bbe57-4761-4484-a8c1-8768c885eaf3' User entered 'No (N)' | System | 09 Aug 2020 04:50:08 |
| | System | 09 Aug 2020 04:50:08 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '164bbe57-4761-4484-a8c1-8768c885eaf3' | System | 09 Aug 2020 04:50:08 |
| User entered 'None (1)' | System | 09 Aug 2020 04:50:08 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '164bbe57-4761-4484-a8c1-8768c885eaf3' User entered '08 Aug 2020 23:50' | System | 09 Aug 2020 04:50:08 |
| | System | 09 Aug 2020 04:50:08 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 5' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:10', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e73689af-d2e6-40d9-983c-02e63e88a182' | System | 10 Aug 2020 05:01:37 |
| User entered 'None (1)' | System | 10 Aug 2020 05:01:37 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e73689af-d2e6-40d9-983c-02e63e88a182' | System | 10 Aug 2020 05:01:37 |
| User entered 'No (N)' | System | 10 Aug 2020 05:01:37 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e73689af-d2e6-40d9-983c-02e63e88a182' | System | 10 Aug 2020 05:01:37 |
| User entered 'No (N)' | System | 10 Aug 2020 05:01:37 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e73689af-d2e6-40d9-983c-02e63e88a182' | System | 10 Aug 2020 05:01:37 |
| User entered 'None (1)' | System | 10 Aug 2020 05:01:37 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e73689af-d2e6-40d9-983c-02e63e88a182' User entered '10 Aug 2020 00:01' | System | 10 Aug 2020 05:01:37 |
| | System | 10 Aug 2020 05:01:37 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '10 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 6' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:24', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '98b49e20-a00a-41d9-b4f5-1070b5de69dd' | System | 11 Aug 2020 04:42:56 |
| User entered 'None (1)' | System | 11 Aug 2020 04:42:56 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:30', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '98b49e20-a00a-41d9-b4f5-1070b5de69dd' User entered 'No (N)' | System | 11 Aug 2020 04:42:56 |
| | System | 11 Aug 2020 04:42:56 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:36', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '98b49e20-a00a-41d9-b4f5-1070b5de69dd' | System | 11 Aug 2020 04:42:56 |
| User entered 'No (N)' | System | 11 Aug 2020 04:42:56 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:45', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '98b49e20-a00a-41d9-b4f5-1070b5de69dd' | System | 11 Aug 2020 04:42:56 |
| User entered 'Does not interfere with activity (2)' | System | 11 Aug 2020 04:42:56 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:42:53', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '98b49e20-a00a-41d9-b4f5-1070b5de69dd' User entered '10 Aug 2020 23:42' | System | 11 Aug 2020 04:42:56 |
| | System | 11 Aug 2020 04:42:56 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '10 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '11 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 7' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9cce0b9b-2ab8-4902-8156-a81861a31720' | System | 12 Aug 2020 05:02:39 |
| User entered 'None (1)' | System | 12 Aug 2020 05:02:39 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9cce0b9b-2ab8-4902-8156-a81861a31720' User entered 'No (N)' | System | 12 Aug 2020 05:02:39 |
| | System | 12 Aug 2020 05:02:39 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:28', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9cce0b9b-2ab8-4902-8156-a81861a31720' User entered 'No (N)' | System | 12 Aug 2020 05:02:39 |
| | System | 12 Aug 2020 05:02:39 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:33', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9cce0b9b-2ab8-4902-8156-a81861a31720' User entered 'None (1)' | System | 12 Aug 2020 05:02:39 |
| | System | 12 Aug 2020 05:02:39 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:37', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9cce0b9b-2ab8-4902-8156-a81861a31720' User entered '12 Aug 2020 00:02' | System | 12 Aug 2020 05:02:39 |
| | System | 12 Aug 2020 05:02:39 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '11 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '12 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' | System | 05 Aug 2020 19:57:53 |
| User entered 'None (0)' | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' | System | 05 Aug 2020 19:57:53 |
| User entered 'None (0)' | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:31', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' User entered 'None (0)' | System | 05 Aug 2020 19:57:53 |
| | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' User entered 'None (0)' | System | 05 Aug 2020 19:57:53 |
| | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:39', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' User entered 'None (0)' | System | 05 Aug 2020 19:57:53 |
| | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:42', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' User entered 'None (0)' | System | 05 Aug 2020 19:57:53 |
| | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:46', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' | System | 05 Aug 2020 19:57:53 |
| User entered 'No (N)' | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-05T14:57:51', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3c0aac0-7cfc-42c4-bba6-8a608eb1bf85' | System | 05 Aug 2020 19:57:53 |
| User entered '05 Aug 2020 14:57' | System | 05 Aug 2020 19:57:53 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 13:43' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 16:13' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| | | |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| | | |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Aug 2020 17:08' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 2' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:04', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' | System | 07 Aug 2020 04:30:38 |
| User entered 'None (0)' | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' | System | 07 Aug 2020 04:30:38 |
| User entered 'None (0)' | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:12', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' | System | 07 Aug 2020 04:30:38 |
| User entered 'None (0)' | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:16', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' User entered 'None (0)' | System | 07 Aug 2020 04:30:38 |
| | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:20', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' User entered 'None (0)' | System | 07 Aug 2020 04:30:38 |
| | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' | System | 07 Aug 2020 04:30:38 |
| User entered 'None (0)' | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:29', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' | System | 07 Aug 2020 04:30:38 |
| User entered 'No (N)' | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-06T23:30:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9bc23a5f-7f29-48ef-bd75-4f09f14c3b77' | System | 07 Aug 2020 04:30:38 |
| User entered '06 Aug 2020 23:30' | System | 07 Aug 2020 04:30:38 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 3' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:03:50', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered 'None (0)' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:04:44', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered 'None (0)' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:05:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered 'None (0)' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:05:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered 'None (0)' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:05:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered 'None (0)' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:05:43', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered 'None (0)' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:05:50', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered 'No (N)' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T00:06:08', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '1c58d035-c50d-4d1d-8c7e-158c1e6ff197' | System | 08 Aug 2020 05:06:10 |
| User entered '08 Aug 2020 00:06' | System | 08 Aug 2020 05:06:10 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 4' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:15', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered 'None (0)' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:19', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered 'None (0)' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered 'None (0)' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered 'None (0)' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:43', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered 'None (0)' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:50:51', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered 'None (0)' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:51:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered 'No (N)' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-08T23:51:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ea62c6e3-fae1-4396-907c-bead344278ea' User entered '08 Aug 2020 23:51' | System | 09 Aug 2020 04:51:09 |
| | System | 09 Aug 2020 04:51:09 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 5' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' User entered 'None (0)' | System | 10 Aug 2020 05:02:15 |
| | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:43', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' User entered 'None (0)' | System | 10 Aug 2020 05:02:15 |
| | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:47', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' User entered 'None (0)' | System | 10 Aug 2020 05:02:15 |
| | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:51', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' User entered 'None (0)' | System | 10 Aug 2020 05:02:15 |
| | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:01:55', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' User entered 'None (0)' | System | 10 Aug 2020 05:02:15 |
| | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:02:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' User entered 'None (0)' | System | 10 Aug 2020 05:02:15 |
| | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:02:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' | System | 10 Aug 2020 05:02:15 |
| User entered 'No (N)' | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T00:02:13', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f969e996-3e7b-42d9-955f-604b971f1e3d' User entered '10 Aug 2020 00:02' | System | 10 Aug 2020 05:02:15 |
| | System | 10 Aug 2020 05:02:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '10 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 6' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:43:08', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' User entered 'None (0)' | System | 11 Aug 2020 04:44:31 |
| | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:43:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' | System | 11 Aug 2020 04:44:31 |
| User entered 'No interference with activity (1)' | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:43:30', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' User entered 'None (0)' | System | 11 Aug 2020 04:44:31 |
| | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:43:40', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' User entered 'Some interference with activity (2)' | System | 11 Aug 2020 04:44:31 |
| | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:43:49', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' User entered 'None (0)' | System | 11 Aug 2020 04:44:31 |
| | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:43:55', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' User entered 'None (0)' | System | 11 Aug 2020 04:44:31 |
| | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:44:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' User entered 'No (N)' | System | 11 Aug 2020 04:44:31 |
| | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-10T23:44:29', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '03f059d3-779c-4268-a12b-2d5dadd15c84' User entered '10 Aug 2020 23:44' | System | 11 Aug 2020 04:44:31 |
| | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '10 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '11 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 7' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:43', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered 'None (0)' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:51', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered 'No interference with activity (1)' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:02:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered 'None (0)' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:03:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered 'No interference with activity (1)' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:03:06', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered 'None (0)' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:03:10', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered 'None (0)' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:03:15', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered 'No (N)' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-12T00:03:18', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '5ce5190d-903a-47cd-9782-aa6dfb5fbf4c' User entered '12 Aug 2020 00:03' | System | 12 Aug 2020 05:03:22 |
| | System | 12 Aug 2020 05:03:22 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '11 Aug 2020 12:00' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '12 Aug 2020 11:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 11 Aug 2020 04:44:31 |
| User entered 'Day 8' | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:03:00

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-13T00:02:04', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b2f772f8-40f2-4119-b0ea-0667f9d3ec22' | System | 13 Aug 2020 05:02:14 |
| User entered 'None (0)' | System | 13 Aug 2020 05:02:14 |

US3092021

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-13T00:02:12', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b2f772f8-40f2-4119-b0ea-0667f9d3ec22' | System | 13 Aug 2020 05:02:14 |
| User entered '13 Aug 2020 00:02' | System | 13 Aug 2020 05:02:14 |

US3092021

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 11 Aug 2020 04:44:31 |
| User entered 'Day 8' | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:03:00

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-13T00:02:24', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2639cb67-6be9-4f7a-bc2c-976ad66b3405' User entered 'None (0)' | System | 13 Aug 2020 05:02:37 |
| | System | 13 Aug 2020 05:02:37 |

US3092021

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-13T00:02:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2639cb67-6be9-4f7a-bc2c-976ad66b3405' | System | 13 Aug 2020 05:02:37 |
| User entered '13 Aug 2020 00:02' | System | 13 Aug 2020 05:02:37 |

US3092021

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 04:44:31 |

US3092021

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 11 Aug 2020 04:42:12 |
| User entered 'Day 8' | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-13T00:02:41', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4a50e844-7c5d-4ae5-8a7a-3da55aea5633' User entered 'No (N)' | System | 13 Aug 2020 05:02:58 |
| | System | 13 Aug 2020 05:02:58 |

US3092021

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-08-13T00:02:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4a50e844-7c5d-4ae5-8a7a-3da55aea5633' User entered '13 Aug 2020 00:02' | System | 13 Aug 2020 05:02:58 |
| | System | 13 Aug 2020 05:02:58 |

US3092021

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '12 Aug 2020 12:00' | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '13 Aug 2020 11:59' | System | 11 Aug 2020 04:42:12 |

US3092021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | (b) (4) System | 17 Aug 2020 19:40:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Catina Adams (b) (4) (b) (4) | 17 Aug 2020 19:40:53 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 10 Aug 2020 13:57:25 |
| User entered 'No (N)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:57:25 |

US3092021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 06:01:31 |
| Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Unable to reach subject until today. Not able to leave message with phone number provided. CLA' (Site from System). | Catina Adams (b) (4) (b) (4) | 17 Aug 2020 19:44:31 |
| User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 17 Aug 2020 19:40:53 |
| User entered '17 Aug 2020' reason for change: Data Entry Error | Catina Adams (b) (4) (b) (4) | 17 Aug 2020 19:40:53 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:57:25 |

US3092021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) | |
| reason for change: Data Entry Error | Catina Adams (b) (4) | 17 Aug 2020 19:40:53 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 13:57:25 |
| | (b) (4) | |

US3092021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | (b) (4) | 17 Aug 2020 19:40:53 |
| Please review and reconcile.' (Site from System). | System | |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | System | 10 Aug 2020 13:57:25 |
| Please review and reconcile.' (Site from System). | | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 13:57:25 |
| | (b) (4) | |

US3092021

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Robert Miranda (b) (4) | 10 Aug 2020 13:57:33 |

US3092021

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 10 Aug 2020 13:57:33 |

US3092021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | (b) (4) | 19 Oct 2020 18:35:53 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System | 10 Aug 2020 13:58:01 |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 13:58:01 |
| | (b) (4) | |

US3092021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 13:58:01 |

US3092021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | destiny robinson (b) (4) | 19 Oct 2020 18:35:53 |
| | (b) (4) | |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | Robert Miranda (b) (4) | 10 Aug 2020 13:58:01 |
| | (b) (4) | |

US3092021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | (b) (4) | 19 Oct 2020 18:35:53 |
| Please review and reconcile.' (Site from System). | System | |
| User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. | System | 10 Aug 2020 13:58:01 |
| Please review and reconcile.' (Site from System). | | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 13:58:01 |
| | (b) (4) | |

US3092021

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Robert Miranda (b) (4) | 10 Aug 2020 13:58:50 |

US3092021

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 10 Aug 2020 13:58:50 |

US3092021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 01 Sep 2020 14:51:04 |

US3092021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '27 Aug 2020' | Catina Adams (b) (4) | 01 Sep 2020 14:51:04 |

US3092021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Contact Made (CONTACT MADE)' | Catina Adams (b) (4) | 01 Sep 2020 14:51:04 |

US3092021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Catina Adams (b) (4) | 01 Sep 2020 14:51:04 |

US3092021

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 01 Sep 2020 14:51:15 |

US3092021

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 01 Sep 2020 14:51:15 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:43:16 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '2 Sep 2020' | Vicki Martinez (b) (4) | 02 Sep 2020 20:43:16 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[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 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Clinic (Clinic)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:43:16 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'VISIT2' | System | 02 Sep 2020 20:43:16 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Vicki Martinez (b) (4) (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '2 Sep 2020' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:18' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '2 Sep 2020 14:18' | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '36.8' C | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (Oral)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '77' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'bpm' | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '18' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'breaths/min' | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '115' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '81' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Vicki Martinez (b) (4) (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '2 Sep 2020' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:55:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 02 Sep 2020 20:55:53 |
| User entered '15:50' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 02 Sep 2020 20:55:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:45:34 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |
| | (b) (4) | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '2 Sep 2020 15:50' | System | 02 Sep 2020 20:55:53 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) | 22 Sep 2020 20:35:39 |
| Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 22 Sep 2020 20:35:39 |
| User entered '97.3' F reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 20:35:39 |
| Amendment Manager: User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) | 16 Sep 2020 23:44:21 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 02 Sep 2020 20:55:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 02 Sep 2020 20:55:53 |
| User entered '97.3' C reason for change: Data Entry Error | Vicki Martinez (b) (4) | 02 Sep 2020 20:55:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:45:34 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |
| | (b) (4) | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) | |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:55:53 |
| User entered empty. | (b) (4) | |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |
| | (b) (4) | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:55:53 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 02 Sep 2020 20:55:53 |
| User entered '80' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 02 Sep 2020 20:55:53 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:45:34 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |
| | (b) (4) | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'bpm' | System | 02 Sep 2020 20:55:53 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:55:53 |
| Query 'Data is required. Please provide.' answered by System | System | 02 Sep 2020 20:55:53 |
| data change (Site from System). | | 02 Sep 2020 20:55:53 |
| User entered '16' reason for change: Data Entry | Vicki Martinez (b) (4) | 02 Sep 2020 20:55:53 |
| Error | (b) (4) | 02 Sep 2020 20:45:34 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 02 Sep 2020 20:45:34 |
| User entered empty. | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |
| | (b) (4) | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'breaths/min' | System | 02 Sep 2020 20:55:53 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '117' reason for change: Data Entry Error | (b) (4) | |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:56:08 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 02 Sep 2020 20:55:53 |
| User entered '88' reason for change: Data Entry Error | | |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:55:53 |
| | (b) (4) | |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 02 Sep 2020 20:45:34 |
| User entered empty. | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |
| | (b) (4) | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 02 Sep 2020 20:55:53 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:56:08 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | System | 02 Sep 2020 20:56:08 |
| User entered '88' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 02 Sep 2020 20:56:08 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 02 Sep 2020 20:45:34 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |
| | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:34 |
| | (b) (4) | |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 02 Sep 2020 20:56:08 |
| User entered empty. | System | 02 Sep 2020 20:45:34 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:49:01 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '2 Sep 2020' | Vicki Martinez (b) (4) | 02 Sep 2020 20:49:01 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '2 Sep 2020' | Vicki Martinez (b) (4) | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '15:13' | Vicki Martinez (b) (4) | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '2 Sep 2020 15:13' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

Which arm was used to give treatment?

| Audit | User | Time (GMT) |
|------------------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Left Arm (LEFT ARM)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'ONCE' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'INTRAMUSCULAR' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:49 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '2 Sep 2020' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:49 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '15:04' | Vicki Martinez (b) (4) | 02 Sep 2020 20:45:49 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '2 Sep 2020 15:04' | System | 02 Sep 2020 20:45:49 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '02 Sep 2020' | Vicki Martinez (b) (4) | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Vicki Martinez (b) (4) (b) (4) | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:58' | Vicki Martinez (b) (4) | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '02 Sep 2020 14:58' | System | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Vicki Martinez (b) (4) (b) (4) | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Vicki Martinez (b) (4) | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered empty. | System | 02 Sep 2020 20:46:09 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Vicki Martinez (b) (4) | 02 Sep 2020 20:44:31 |

US3092021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '1' | System | 02 Sep 2020 20:44:31 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:51:31', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f4694935-a940-43e1-9f6f-82e3fc15acb0' User entered 'Yes (Y)' | System | 02 Sep 2020 20:52:10 |
| | System | 02 Sep 2020 20:52:10 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:51:53', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f4694935-a940-43e1-9f6f-82e3fc15acb0' User entered '97.3' | System | 02 Sep 2020 20:52:10 |
| | System | 02 Sep 2020 20:52:10 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:51:59', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f4694935-a940-43e1-9f6f-82e3fc15acb0' | System | 02 Sep 2020 20:52:10 |
| User entered 'No (N)' | System | 02 Sep 2020 20:52:10 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:07', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f4694935-a940-43e1-9f6f-82e3fc15acb0' | System | 02 Sep 2020 20:52:10 |
| User entered '02 Sep 2020 15:52' | System | 02 Sep 2020 20:52:10 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 15:33' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 18:03' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:24:51', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0d10f8a2-6c2e-4d91-b742-e263be75ec8a' User entered 'Yes (Y)' | System | 03 Sep 2020 04:25:26 |
| | System | 03 Sep 2020 04:25:26 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:25:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0d10f8a2-6c2e-4d91-b742-e263be75ec8a' User entered '96.8' | System | 03 Sep 2020 04:25:26 |
| | System | 03 Sep 2020 04:25:26 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:25:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0d10f8a2-6c2e-4d91-b742-e263be75ec8a' User entered 'No (N)' | System | 03 Sep 2020 04:25:26 |
| | System | 03 Sep 2020 04:25:26 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:25:24', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0d10f8a2-6c2e-4d91-b742-e263be75ec8a' User entered '02 Sep 2020 23:25' | System | 03 Sep 2020 04:25:26 |
| | System | 03 Sep 2020 04:25:26 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 18:58' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 2' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:04', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b73fb199-59f6-487e-94ad-ee00aebbce72' | System | 04 Sep 2020 04:48:28 |
| User entered 'Yes (Y)' | System | 04 Sep 2020 04:48:28 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b73fb199-59f6-487e-94ad-ee00aebbce72' | System | 04 Sep 2020 04:48:28 |
| User entered '97.6' | System | 04 Sep 2020 04:48:28 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:20', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b73fb199-59f6-487e-94ad-ee00aebbce72' | System | 04 Sep 2020 04:48:28 |
| User entered 'No (N)' | System | 04 Sep 2020 04:48:28 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b73fb199-59f6-487e-94ad-ee00aebbce72' | System | 04 Sep 2020 04:48:28 |
| User entered '03 Sep 2020 23:48' | System | 04 Sep 2020 04:48:28 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 3' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e3afa2c8-1658-4524-8edb-ae8a1d3bf485' | System | 05 Sep 2020 05:01:36 |
| User entered 'Yes (Y)' | System | 05 Sep 2020 05:01:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e3afa2c8-1658-4524-8edb-ae8a1d3bf485' User entered '97.5' | System | 05 Sep 2020 05:01:36 |
| | System | 05 Sep 2020 05:01:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e3afa2c8-1658-4524-8edb-ae8a1d3bf485' | System | 05 Sep 2020 05:01:36 |
| User entered 'No (N)' | System | 05 Sep 2020 05:01:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e3afa2c8-1658-4524-8edb-ae8a1d3bf485' | System | 05 Sep 2020 05:01:36 |
| User entered '05 Sep 2020 00:01' | System | 05 Sep 2020 05:01:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 4' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:30:28', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '350f3de9-b9a2-4768-9228-f0023d68e9aa' User entered 'Yes (Y)' | System | 06 Sep 2020 06:30:50 |
| | System | 06 Sep 2020 06:30:50 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:30:36', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '350f3de9-b9a2-4768-9228-f0023d68e9aa' User entered '97.2' | System | 06 Sep 2020 06:30:50 |
| | System | 06 Sep 2020 06:30:50 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:30:44', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '350f3de9-b9a2-4768-9228-f0023d68e9aa' | System | 06 Sep 2020 06:30:50 |
| User entered 'No (N)' | System | 06 Sep 2020 06:30:50 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:30:48', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '350f3de9-b9a2-4768-9228-f0023d68e9aa' User entered '06 Sep 2020 01:30' | System | 06 Sep 2020 06:30:50 |
| | System | 06 Sep 2020 06:30:50 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 5' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:23:19', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '6b45e44e-e3d5-48ec-ab42-939753b66d1d' User entered 'Yes (Y)' | System | 07 Sep 2020 08:23:44 |
| | System | 07 Sep 2020 08:23:44 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:23:30', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '6b45e44e-e3d5-48ec-ab42-939753b66d1d' User entered '96.6' | System | 07 Sep 2020 08:23:44 |
| | System | 07 Sep 2020 08:23:44 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:23:37', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '6b45e44e-e3d5-48ec-ab42-939753b66d1d' User entered 'No (N)' | System | 07 Sep 2020 08:23:44 |
| | System | 07 Sep 2020 08:23:44 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:23:41', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '6b45e44e-e3d5-48ec-ab42-939753b66d1d' User entered '07 Sep 2020 03:23' | System | 07 Sep 2020 08:23:44 |
| | System | 07 Sep 2020 08:23:44 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 6' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:16:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ccab1254-6175-4c89-a278-748a87354363' User entered 'Yes (Y)' | System | 08 Sep 2020 03:17:43 |
| | System | 08 Sep 2020 03:17:43 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:16:42', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ccab1254-6175-4c89-a278-748a87354363' User entered '97.8' | System | 08 Sep 2020 03:17:43 |
| | System | 08 Sep 2020 03:17:43 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:17:18', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ccab1254-6175-4c89-a278-748a87354363' User entered 'No (N)' | System | 08 Sep 2020 03:17:43 |
| | System | 08 Sep 2020 03:17:43 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:17:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ccab1254-6175-4c89-a278-748a87354363' User entered '07 Sep 2020 22:17' | System | 08 Sep 2020 03:17:43 |
| | System | 08 Sep 2020 03:17:43 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 7' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:27:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '228c961a-a288-4a95-b829-48be8c256910' User entered 'Yes (Y)' | System | 09 Sep 2020 03:27:56 |
| | System | 09 Sep 2020 03:27:56 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:27:45', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '228c961a-a288-4a95-b829-48be8c256910' User entered '97.2' | System | 09 Sep 2020 03:27:56 |
| | System | 09 Sep 2020 03:27:56 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:27:49', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '228c961a-a288-4a95-b829-48be8c256910' | System | 09 Sep 2020 03:27:56 |
| User entered 'No (N)' | System | 09 Sep 2020 03:27:56 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:27:53', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '228c961a-a288-4a95-b829-48be8c256910' User entered '08 Sep 2020 22:27' | System | 09 Sep 2020 03:27:56 |
| | System | 09 Sep 2020 03:27:56 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:50:41', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e487118a-160b-42f2-aa4d-c48adf7ac97d' | System | 02 Sep 2020 20:51:19 |
| User entered 'None (1)' | System | 02 Sep 2020 20:51:19 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:50:52', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e487118a-160b-42f2-aa4d-c48adf7ac97d' User entered 'No (N)' | System | 02 Sep 2020 20:51:19 |
| | System | 02 Sep 2020 20:51:19 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:50:57', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e487118a-160b-42f2-aa4d-c48adf7ac97d' User entered 'No (N)' | System | 02 Sep 2020 20:51:19 |
| | System | 02 Sep 2020 20:51:19 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:51:02', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e487118a-160b-42f2-aa4d-c48adf7ac97d' | System | 02 Sep 2020 20:51:19 |
| User entered 'None (1)' | System | 02 Sep 2020 20:51:19 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:51:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'e487118a-160b-42f2-aa4d-c48adf7ac97d' User entered '02 Sep 2020 15:51' | System | 02 Sep 2020 20:51:19 |
| | System | 02 Sep 2020 20:51:19 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 15:33' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 18:03' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:25:55', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'c119b54f-0ae0-4b79-b5f4-fc7134a9633f' User entered 'None (1)' | System | 03 Sep 2020 04:26:15 |
| | System | 03 Sep 2020 04:26:15 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'c119b54f-0ae0-4b79-b5f4-fc7134a9633f' User entered 'No (N)' | System | 03 Sep 2020 04:26:15 |
| | System | 03 Sep 2020 04:26:15 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'c119b54f-0ae0-4b79-b5f4-fc7134a9633f' User entered 'No (N)' | System | 03 Sep 2020 04:26:15 |
| | System | 03 Sep 2020 04:26:15 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'c119b54f-0ae0-4b79-b5f4-fc7134a9633f' | System | 03 Sep 2020 04:26:15 |
| User entered 'None (1)' | System | 03 Sep 2020 04:26:15 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'c119b54f-0ae0-4b79-b5f4-fc7134a9633f' User entered '02 Sep 2020 23:26' | System | 03 Sep 2020 04:26:15 |
| | System | 03 Sep 2020 04:26:15 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 18:58' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 2' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:33', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '190c2517-1886-4cab-8507-d339f0fce4ac' | System | 04 Sep 2020 04:48:49 |
| User entered 'None (1)' | System | 04 Sep 2020 04:48:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:37', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '190c2517-1886-4cab-8507-d339f0fce4ac' User entered 'No (N)' | System | 04 Sep 2020 04:48:49 |
| | System | 04 Sep 2020 04:48:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:40', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '190c2517-1886-4cab-8507-d339f0fce4ac' | System | 04 Sep 2020 04:48:49 |
| User entered 'No (N)' | System | 04 Sep 2020 04:48:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:42', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '190c2517-1886-4cab-8507-d339f0fce4ac' | System | 04 Sep 2020 04:48:49 |
| User entered 'None (1)' | System | 04 Sep 2020 04:48:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:46', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '190c2517-1886-4cab-8507-d339f0fce4ac' User entered '03 Sep 2020 23:48' | System | 04 Sep 2020 04:48:49 |
| | System | 04 Sep 2020 04:48:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 3' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4bab6bd3-4b62-4e70-b3a9-33bba4cd2cff' | System | 05 Sep 2020 05:01:55 |
| User entered 'None (1)' | System | 05 Sep 2020 05:01:55 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:41', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4bab6bd3-4b62-4e70-b3a9-33bba4cd2cff' User entered 'No (N)' | System | 05 Sep 2020 05:01:55 |
| | System | 05 Sep 2020 05:01:55 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:43', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4bab6bd3-4b62-4e70-b3a9-33bba4cd2cff' User entered 'No (N)' | System | 05 Sep 2020 05:01:55 |
| | System | 05 Sep 2020 05:01:55 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:46', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4bab6bd3-4b62-4e70-b3a9-33bba4cd2cff' User entered 'None (1)' | System | 05 Sep 2020 05:01:55 |
| | System | 05 Sep 2020 05:01:55 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:50', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4bab6bd3-4b62-4e70-b3a9-33bba4cd2cff' User entered '05 Sep 2020 00:01' | System | 05 Sep 2020 05:01:55 |
| | System | 05 Sep 2020 05:01:55 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 4' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:30:54', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '692b2e41-ac95-4aea-991d-0f97d79c9618' | System | 06 Sep 2020 06:31:07 |
| User entered 'None (1)' | System | 06 Sep 2020 06:31:07 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:30:57', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '692b2e41-ac95-4aea-991d-0f97d79c9618' User entered 'No (N)' | System | 06 Sep 2020 06:31:07 |
| | System | 06 Sep 2020 06:31:07 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:30:59', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '692b2e41-ac95-4aea-991d-0f97d79c9618' User entered 'No (N)' | System | 06 Sep 2020 06:31:07 |
| | System | 06 Sep 2020 06:31:07 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '692b2e41-ac95-4aea-991d-0f97d79c9618' | System | 06 Sep 2020 06:31:07 |
| User entered 'None (1)' | System | 06 Sep 2020 06:31:07 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '692b2e41-ac95-4aea-991d-0f97d79c9618' User entered '06 Sep 2020 01:31' | System | 06 Sep 2020 06:31:07 |
| | System | 06 Sep 2020 06:31:07 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 5' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:23:59', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '419beb8a-3ec6-4c9b-bcd2-18ea56a19183' | System | 07 Sep 2020 08:24:16 |
| User entered 'None (1)' | System | 07 Sep 2020 08:24:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:03', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '419beb8a-3ec6-4c9b-bcd2-18ea56a19183' User entered 'No (N)' | System | 07 Sep 2020 08:24:16 |
| | System | 07 Sep 2020 08:24:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:07', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '419beb8a-3ec6-4c9b-bcd2-18ea56a19183' User entered 'No (N)' | System | 07 Sep 2020 08:24:16 |
| | System | 07 Sep 2020 08:24:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:11', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '419beb8a-3ec6-4c9b-bcd2-18ea56a19183' User entered 'None (1)' | System | 07 Sep 2020 08:24:16 |
| | System | 07 Sep 2020 08:24:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:15', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '419beb8a-3ec6-4c9b-bcd2-18ea56a19183' User entered '07 Sep 2020 03:24' | System | 07 Sep 2020 08:24:16 |
| | System | 07 Sep 2020 08:24:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 6' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:17:47', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd7997a3d-574d-4c35-a0ff-4c5ed22d7aab' | System | 08 Sep 2020 03:18:09 |
| User entered 'None (1)' | System | 08 Sep 2020 03:18:09 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:17:52', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd7997a3d-574d-4c35-a0ff-4c5ed22d7aab' | System | 08 Sep 2020 03:18:09 |
| User entered 'No (N)' | System | 08 Sep 2020 03:18:09 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:17:55', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd7997a3d-574d-4c35-a0ff-4c5ed22d7aab' | System | 08 Sep 2020 03:18:09 |
| User entered 'No (N)' | System | 08 Sep 2020 03:18:09 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:17:59', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd7997a3d-574d-4c35-a0ff-4c5ed22d7aab' | System | 08 Sep 2020 03:18:09 |
| User entered 'None (1)' | System | 08 Sep 2020 03:18:09 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd7997a3d-574d-4c35-a0ff-4c5ed22d7aab' User entered '07 Sep 2020 22:18' | System | 08 Sep 2020 03:18:09 |
| | System | 08 Sep 2020 03:18:09 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 7' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:27:58', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0b12e5a2-13ae-43b9-81be-e09e766e56ad' User entered 'None (1)' | System | 09 Sep 2020 03:28:12 |
| | System | 09 Sep 2020 03:28:12 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0b12e5a2-13ae-43b9-81be-e09e766e56ad' User entered 'No (N)' | System | 09 Sep 2020 03:28:12 |
| | System | 09 Sep 2020 03:28:12 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:02', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0b12e5a2-13ae-43b9-81be-e09e766e56ad' User entered 'No (N)' | System | 09 Sep 2020 03:28:12 |
| | System | 09 Sep 2020 03:28:12 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0b12e5a2-13ae-43b9-81be-e09e766e56ad' | System | 09 Sep 2020 03:28:12 |
| User entered 'None (1)' | System | 09 Sep 2020 03:28:12 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:08', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0b12e5a2-13ae-43b9-81be-e09e766e56ad' User entered '08 Sep 2020 22:28' | System | 09 Sep 2020 03:28:12 |
| | System | 09 Sep 2020 03:28:12 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:21', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered 'None (0)' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:24', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered 'None (0)' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered 'None (0)' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:31', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered 'None (0)' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:35', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered 'None (0)' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:37', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered 'None (0)' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:42', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered 'No (N)' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T15:52:46', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '3f823f0c-4950-4991-8db8-ce35df5fe469' User entered '02 Sep 2020 15:52' | System | 02 Sep 2020 20:52:49 |
| | System | 02 Sep 2020 20:52:49 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 15:33' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 18:03' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 1, after vaccination (at home)' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:20', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered 'None (0)' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered 'None (0)' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered 'None (0)' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:29', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered 'None (0)' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:33', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered 'None (0)' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:36', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered 'None (0)' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:41', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered 'No (N)' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-02T23:26:44', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '4f17f85e-e781-439e-afd0-5d016c64dfcf' User entered '02 Sep 2020 23:26' | System | 03 Sep 2020 04:26:46 |
| | System | 03 Sep 2020 04:26:46 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '02 Sep 2020 18:58' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '03 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 2' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:52', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' User entered 'None (0)' | System | 04 Sep 2020 04:49:16 |
| | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:55', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' | System | 04 Sep 2020 04:49:16 |
| User entered 'None (0)' | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:48:59', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' User entered 'None (0)' | System | 04 Sep 2020 04:49:16 |
| | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:49:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' | System | 04 Sep 2020 04:49:16 |
| User entered 'None (0)' | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:49:04', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' | System | 04 Sep 2020 04:49:16 |
| User entered 'None (0)' | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:49:07', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' | System | 04 Sep 2020 04:49:16 |
| User entered 'None (0)' | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:49:10', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' | System | 04 Sep 2020 04:49:16 |
| User entered 'No (N)' | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-03T23:49:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'f1825818-20e5-428c-9e6e-f291a0f2f152' | System | 04 Sep 2020 04:49:16 |
| User entered '03 Sep 2020 23:49' | System | 04 Sep 2020 04:49:16 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '03 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '04 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 3' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered 'None (0)' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:01:58', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered 'None (0)' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:02:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered 'None (0)' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:02:03', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered 'None (0)' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:02:06', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered 'None (0)' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:02:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered 'None (0)' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:02:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered 'No (N)' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-05T00:02:18', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '8270c130-5b20-46de-b69f-a177f15874d6' User entered '05 Sep 2020 00:02' | System | 05 Sep 2020 05:02:20 |
| | System | 05 Sep 2020 05:02:20 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '04 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 4' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:11', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered 'None (0)' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered 'None (0)' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered 'None (0)' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:20', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered 'None (0)' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered 'None (0)' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered 'None (0)' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:29', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered 'No (N)' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-06T01:31:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b85f2e63-5363-453a-8c4b-3702756a1078' User entered '06 Sep 2020 01:31' | System | 06 Sep 2020 06:31:35 |
| | System | 06 Sep 2020 06:31:35 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '05 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 5' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered 'None (0)' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered 'None (0)' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:29', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered 'None (0)' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered 'None (0)' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered 'None (0)' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:41', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered 'None (0)' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:46', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered 'No (N)' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T03:24:49', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'd20e7361-1c64-4582-bc2d-d1e4af0314fe' User entered '07 Sep 2020 03:24' | System | 07 Sep 2020 08:24:51 |
| | System | 07 Sep 2020 08:24:51 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '06 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 6' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:12', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered 'None (0)' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:16', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered 'None (0)' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:18', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered 'None (0)' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered 'None (0)' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:25', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered 'None (0)' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:28', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered 'None (0)' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered 'No (N)' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-07T22:18:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '9ddc3657-cde0-4004-a32c-428c967fb381' User entered '07 Sep 2020 22:18' | System | 08 Sep 2020 03:18:41 |
| | System | 08 Sep 2020 03:18:41 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '07 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 02 Sep 2020 20:48:52 |
| User entered 'Day 7' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:13', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered 'None (0)' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:16', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered 'None (0)' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:19', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered 'None (0)' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered 'None (0)' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:25', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered 'None (0)' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered 'None (0)' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

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) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:30', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered 'No (N)' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-09-08T22:28:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7c553a81-c03b-4d52-aedc-dd5857c10dc5' User entered '08 Sep 2020 22:28' | System | 09 Sep 2020 03:28:36 |
| | System | 09 Sep 2020 03:28:36 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '08 Sep 2020 12:00' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:03:00

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User entered '09 Sep 2020 11:59' | System | 02 Sep 2020 20:48:52 |

US3092021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:49 |

US3092021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:49 |

US3092021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:49 |

US3092021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:49 |

US3092021

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:32:26 |

US3092021

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 06 Oct 2020 22:32:26 |

US3092021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:56 |

US3092021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:56 |

US3092021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:56 |

US3092021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:48:56 |

US3092021

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:32:35 |

US3092021

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 06 Oct 2020 22:32:35 |

US3092021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:49:01 |

US3092021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:49:01 |

US3092021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:49:01 |

US3092021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 22:49:01 |

US3092021

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:32:45 |

US3092021

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 06 Oct 2020 22:32:45 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:33:42 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '6 Oct 2020' | Catina Adams (b) (4) | 06 Oct 2020 22:33:42 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[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 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Clinic (Clinic)' | Catina Adams (b) (4) | 06 Oct 2020 22:33:42 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'VISIT3' | System | 06 Oct 2020 22:33:42 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '6 Oct 2020' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:28' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '6 Oct 2020 14:28' | System | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '97.7' F | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (Oral)' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '80' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'bpm' | System | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '17' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'breaths/min' | System | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '104' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '73' | Catina Adams (b) (4) | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'mmHg' | System | 06 Oct 2020 22:41:51 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:42:13 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '6 Oct 2020' | Catina Adams (b) (4) | 06 Oct 2020 22:42:13 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:42:41 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '6 Oct 2020' | Catina Adams (b) (4) | 06 Oct 2020 22:42:41 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:56' | Catina Adams (b) (4) | 06 Oct 2020 22:42:41 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered '6 Oct 2020 14:56' | System | 06 Oct 2020 22:42:41 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 06 Oct 2020 22:42:47 |

US3092021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 06 Oct 2020 22:42:47 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 64' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-10-06T16:20:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '990bfcf8-db3a-4196-acb9-9a08c8a20787' | System | 06 Oct 2020 21:21:13 |
| User entered 'No (N)' | System | 06 Oct 2020 21:21:13 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-10-06T16:21:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '990bfcf8-db3a-4196-acb9-9a08c8a20787' | System | 06 Oct 2020 21:21:13 |
| User entered 'No (N)' | System | 06 Oct 2020 21:21:13 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-10-06T16:21:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '990bfcf8-db3a-4196-acb9-9a08c8a20787' User entered '06 Oct 2020 16:21:09' | System | 06 Oct 2020 21:21:13 |
| | System | 06 Oct 2020 21:21:13 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '05 Oct 2020 00:01' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '09 Oct 2020 23:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 71' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '12 Oct 2020 00:01' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '16 Oct 2020 23:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 78' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
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US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '19 Oct 2020 00:01' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '23 Oct 2020 23:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 92' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-03T02:29:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '62a7462d-b827-4370-b9cc-b4a1ce661d59' | System | 03 Nov 2020 08:29:36 |
| User entered 'No (N)' | System | 03 Nov 2020 08:29:36 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-03T02:29:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '62a7462d-b827-4370-b9cc-b4a1ce661d59' | System | 03 Nov 2020 08:29:36 |
| User entered 'No (N)' | System | 03 Nov 2020 08:29:36 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-03T02:29:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '62a7462d-b827-4370-b9cc-b4a1ce661d59' User entered '03 Nov 2020 02:29:32' | System | 03 Nov 2020 08:29:36 |
| | System | 03 Nov 2020 08:29:36 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '02 Nov 2020 00:01' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '06 Nov 2020 23:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 99' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
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US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
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US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
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US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
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US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
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US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
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US3092021

Folder: 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.](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
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US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
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| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '09 Nov 2020 00:01' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 13:38:11 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '13 Nov 2020 23:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered 'Day 106' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| User closed query 'Per DM CLR: 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | | 26 Jan 2021 14:49:57 |
| Query 'Per DM CLR: 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE has been updated. ' (Site from DM). | | 07 Jan 2021 15:41:06 |
| User opened query 'Per DM CLR: 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | | 16 Dec 2020 15:19:23 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-18T22:00:21', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '45bcb5f1-a1f6-4908-b067-04198eb8369d' | System | 19 Nov 2020 04:01:33 |
| User entered 'Yes (Y)' | System | 19 Nov 2020 04:01:33 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-18T22:00:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '45bcb5f1-a1f6-4908-b067-04198eb8369d' | System | 19 Nov 2020 04:01:33 |
| User entered 'No (N)' | System | 19 Nov 2020 04:01:33 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-18T22:00:35', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '45bcb5f1-a1f6-4908-b067-04198eb8369d' User entered 'No (N)' | System | 19 Nov 2020 04:01:33 |
| | System | 19 Nov 2020 04:01:33 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-18T22:00:56', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '45bcb5f1-a1f6-4908-b067-04198eb8369d' | System | 19 Nov 2020 04:01:33 |
| User entered 'Yes (Y)' | System | 19 Nov 2020 04:01:33 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-18T22:01:08', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '45bcb5f1-a1f6-4908-b067-04198eb8369d' | System | 19 Nov 2020 04:01:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 19 Nov 2020 04:01:33 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-18T22:01:21', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '45bcb5f1-a1f6-4908-b067-04198eb8369d' User entered '18 Nov 2020 22:01:21' | System | 19 Nov 2020 04:01:33 |
| | System | 19 Nov 2020 04:01:33 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '16 Nov 2020 00:01' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 14:03:29 |
| Data entry locked. | System | 05 Aug 2020 18:28:15 |
| User entered '20 Nov 2020 23:59' | System | 05 Aug 2020 18:28:15 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

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) |
|---|------------------|----------------------|
| User closed query 'Per DM CLR: 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 16 Mar 2021 19:25:54 |
| Query 'Per DM CLR: 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'PER SOURCE, SUBJECT WAS CONTACTED AND AE WAS CAPTURED ON AE LOG, SOURCE AND EDC' (Site from DM). | (b) (4), (b) (6) | 11 Mar 2021 17:23:22 |
| User opened query 'Per DM CLR: 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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 09:49:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-28T06:07:42', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'cb493f47-7da7-4bb1-b631-c7919d88aff1' | System | 28 Nov 2020 12:08:50 |
| User entered 'Yes (Y)' | System | 28 Nov 2020 12:08:50 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-28T06:07:51', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'cb493f47-7da7-4bb1-b631-c7919d88aff1' User entered 'No (N)' | System | 28 Nov 2020 12:08:50 |
| | System | 28 Nov 2020 12:08:50 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-28T06:08:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'cb493f47-7da7-4bb1-b631-c7919d88aff1' User entered 'No (N)' | System | 28 Nov 2020 12:08:50 |
| | System | 28 Nov 2020 12:08:50 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-28T06:08:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'cb493f47-7da7-4bb1-b631-c7919d88aff1' | System | 28 Nov 2020 12:08:50 |
| User entered 'Yes (Y)' | System | 28 Nov 2020 12:08:50 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Please 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-28T06:08:29', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'cb493f47-7da7-4bb1-b631-c7919d88aff1' | System | 28 Nov 2020 12:08:50 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 28 Nov 2020 12:08:50 |

US3092021

Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-11-28T06:08:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'cb493f47-7da7-4bb1-b631-c7919d88aff1' User entered '28 Nov 2020 06:08:38' | System | 28 Nov 2020 12:08:50 |
| | System | 28 Nov 2020 12:08:50 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-04T15:59:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '73f660ac-373d-47a9-8e2b-71111b8d23f1' User entered 'No (N)' | System | 04 Dec 2020 21:59:29 |
| | System | 04 Dec 2020 21:59:29 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-04T15:59:22', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '73f660ac-373d-47a9-8e2b-71111b8d23f1' User entered 'No (N)' | System | 04 Dec 2020 21:59:29 |
| | System | 04 Dec 2020 21:59:29 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-04T15:59:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '73f660ac-373d-47a9-8e2b-71111b8d23f1' User entered '04 Dec 2020 15:59:26' | System | 04 Dec 2020 21:59:29 |
| | System | 04 Dec 2020 21:59:29 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-13T01:26:21', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '634ea870-bdfe-47ac-898c-23475cbcebe3' User entered 'No (N)' | System | 13 Dec 2020 07:26:56 |
| | System | 13 Dec 2020 07:26:56 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-13T01:26:25', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '634ea870-bdfe-47ac-898c-23475cbcebe3' User entered 'No (N)' | System | 13 Dec 2020 07:26:56 |
| | System | 13 Dec 2020 07:26:56 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-13T01:26:52', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '634ea870-bdfe-47ac-898c-23475cbcebe3' User entered '13 Dec 2020 01:26:52' | System | 13 Dec 2020 07:26:56 |
| | System | 13 Dec 2020 07:26:56 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-18T15:34:04', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '36ac3563-b19b-4315-b372-4159653829ce' User entered 'No (N)' | System | 18 Dec 2020 21:34:20 |
| | System | 18 Dec 2020 21:34:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-18T15:34:10', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '36ac3563-b19b-4315-b372-4159653829ce' User entered 'No (N)' | System | 18 Dec 2020 21:34:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-18T15:34:17', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '36ac3563-b19b-4315-b372-4159653829ce' User entered '18 Dec 2020 15:34:17' | System | 18 Dec 2020 21:34:20 |
| | System | 18 Dec 2020 21:34:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-26T17:05:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '69a9151a-a7ea-48d9-887e-b6d0c43750ff' User entered 'No (N)' | System | 26 Dec 2020 23:06:34 |
| | System | 26 Dec 2020 23:06:34 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-26T17:05:41', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '69a9151a-a7ea-48d9-887e-b6d0c43750ff' User entered 'Yes (Y)' | System | 26 Dec 2020 23:06:34 |
| | System | 26 Dec 2020 23:06:34 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Please 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-26T17:06:09', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '69a9151a-a7ea-48d9-887e-b6d0c43750ff' | System | 26 Dec 2020 23:06:34 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 26 Dec 2020 23:06:34 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2020-12-26T17:06:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '69a9151a-a7ea-48d9-887e-b6d0c43750ff' User entered '26 Dec 2020 17:06:23' | System | 26 Dec 2020 23:06:34 |
| | System | 26 Dec 2020 23:06:34 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-01T17:55:27', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2e7490ab-bea0-4bd0-8d74-456c10360dfb' User entered 'No (N)' | System | 01 Jan 2021 23:55:36 |
| | System | 01 Jan 2021 23:55:36 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-01T17:55:30', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2e7490ab-bea0-4bd0-8d74-456c10360dfb' User entered 'No (N)' | System | 01 Jan 2021 23:55:36 |
| | System | 01 Jan 2021 23:55:36 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-01T17:55:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '2e7490ab-bea0-4bd0-8d74-456c10360dfb' User entered '01 Jan 2021 17:55:34' | System | 01 Jan 2021 23:55:36 |
| | System | 01 Jan 2021 23:55:36 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-10T04:44:07', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '26e8b489-fb80-4964-aca4-05a9a26748d5' User entered 'No (N)' | System | 10 Jan 2021 10:44:18 |
| | System | 10 Jan 2021 10:44:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-10T04:44:10', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '26e8b489-fb80-4964-aca4-05a9a26748d5' User entered 'No (N)' | System | 10 Jan 2021 10:44:18 |
| | System | 10 Jan 2021 10:44:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-10T04:44:14', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '26e8b489-fb80-4964-aca4-05a9a26748d5' User entered '10 Jan 2021 04:44:14' | System | 10 Jan 2021 10:44:18 |
| | System | 10 Jan 2021 10:44:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-22T17:37:05', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '934ae5c5-fcb0-49d0-8b81-ba75a770aea2' User entered 'No (N)' | System | 22 Jan 2021 23:37:14 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-22T17:37:08', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '934ae5c5-fcb0-49d0-8b81-ba75a770aea2' User entered 'No (N)' | System | 22 Jan 2021 23:37:14 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-22T17:37:12', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '934ae5c5-fcb0-49d0-8b81-ba75a770aea2' User entered '22 Jan 2021 17:37:12' | System | 22 Jan 2021 23:37:14 |
| | System | 22 Jan 2021 23:37:14 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-29T11:43:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '71d88b48-ccd6-4e71-a833-09baf4a7d36b' | System | 29 Jan 2021 17:44:15 |
| User entered 'Yes (Y)' | System | 29 Jan 2021 17:44:15 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-29T11:43:10', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '71d88b48-ccd6-4e71-a833-09baf4a7d36b' | System | 29 Jan 2021 17:44:15 |
| User entered 'No (N)' | System | 29 Jan 2021 17:44:15 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-29T11:43:23', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '71d88b48-ccd6-4e71-a833-09baf4a7d36b' User entered 'No (N)' | System | 29 Jan 2021 17:44:15 |
| | System | 29 Jan 2021 17:44:15 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-29T11:43:31', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '71d88b48-ccd6-4e71-a833-09baf4a7d36b' User entered 'Yes (Y)' | System | 29 Jan 2021 17:44:15 |
| | System | 29 Jan 2021 17:44:15 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Please 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-29T11:43:48', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '71d88b48-ccd6-4e71-a833-09baf4a7d36b' | System | 29 Jan 2021 17:44:15 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 29 Jan 2021 17:44:15 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-01-29T11:44:01', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '71d88b48-ccd6-4e71-a833-09baf4a7d36b' User entered '29 Jan 2021 11:44:01' | System | 29 Jan 2021 17:44:15 |
| | System | 29 Jan 2021 17:44:15 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-06T05:17:26', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '87cce60d-92cd-400f-9027-0acd7f34731c' User entered 'Yes (Y)' | System | 06 Feb 2021 11:18:20 |
| | System | 06 Feb 2021 11:18:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-06T05:17:32', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '87cce60d-92cd-400f-9027-0acd7f34731c' | System | 06 Feb 2021 11:18:20 |
| User entered 'No (N)' | System | 06 Feb 2021 11:18:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-06T05:17:39', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '87cce60d-92cd-400f-9027-0acd7f34731c' User entered 'No (N)' | System | 06 Feb 2021 11:18:20 |
| | System | 06 Feb 2021 11:18:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-06T05:17:54', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '87cce60d-92cd-400f-9027-0acd7f34731c' User entered 'Yes (Y)' | System | 06 Feb 2021 11:18:20 |
| | System | 06 Feb 2021 11:18:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Please 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-06T05:18:07', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '87cce60d-92cd-400f-9027-0acd7f34731c' | System | 06 Feb 2021 11:18:20 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 06 Feb 2021 11:18:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-06T05:18:11', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '87cce60d-92cd-400f-9027-0acd7f34731c' User entered '06 Feb 2021 05:18:11' | System | 06 Feb 2021 11:18:20 |
| | System | 06 Feb 2021 11:18:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-14T19:00:39', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '420bb9b5-32aa-4e01-a862-0fa633015e1c' User entered 'No (N)' | System | 15 Feb 2021 01:01:12 |
| | System | 15 Feb 2021 01:01:12 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-14T19:00:44', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '420bb9b5-32aa-4e01-a862-0fa633015e1c' User entered 'No (N)' | System | 15 Feb 2021 01:01:12 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-14T19:00:48', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '420bb9b5-32aa-4e01-a862-0fa633015e1c' User entered '14 Feb 2021 19:00:48' | System | 15 Feb 2021 01:01:12 |
| | System | 15 Feb 2021 01:01:12 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-19T00:02:30', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '522a4908-c65d-480e-8c68-6782d864d2b6' | System | 19 Feb 2021 06:02:42 |
| User entered 'No (N)' | System | 19 Feb 2021 06:02:42 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-19T00:02:34', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '522a4908-c65d-480e-8c68-6782d864d2b6' | System | 19 Feb 2021 06:02:42 |
| User entered 'No (N)' | System | 19 Feb 2021 06:02:42 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-19T00:02:38', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '522a4908-c65d-480e-8c68-6782d864d2b6' | System | 19 Feb 2021 06:02:42 |
| User entered '19 Feb 2021 00:02:38' | System | 19 Feb 2021 06:02:42 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-26T18:17:03-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '892916e7-f11e-4654-a107-5d78e33deda3' User entered 'No (N)' | System | 27 Feb 2021 00:19:26 |
| | System | 27 Feb 2021 00:19:26 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-26T18:17:08-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '892916e7-f11e-4654-a107-5d78e33deda3' User entered 'No (N)' | System | 27 Feb 2021 00:19:26 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-02-26T18:17:12-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '892916e7-f11e-4654-a107-5d78e33deda3' User entered '27 Feb 2021 00:17:12' | System | 27 Feb 2021 00:19:26 |
| | System | 27 Feb 2021 00:19:26 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-05T01:12:02-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'abb16c99-3d71-4899-9602-8beaaf48bcfe' | System | 05 Mar 2021 07:12:18 |
| User entered 'No (N)' | System | 05 Mar 2021 07:12:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-05T01:12:08-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'abb16c99-3d71-4899-9602-8beaaf48bcfe' | System | 05 Mar 2021 07:12:18 |
| User entered 'No (N)' | System | 05 Mar 2021 07:12:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-05T01:12:13-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'abb16c99-3d71-4899-9602-8beaaf48bcfe' User entered '05 Mar 2021 01:12:13' | System | 05 Mar 2021 07:12:18 |
| | System | 05 Mar 2021 07:12:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-12T00:03:04-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '341ab3cf-bbb1-4966-bd33-6d2d159c824b' | System | 12 Mar 2021 06:03:20 |
| User entered 'No (N)' | System | 12 Mar 2021 06:03:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-12T00:03:10-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '341ab3cf-bbb1-4966-bd33-6d2d159c824b' | System | 12 Mar 2021 06:03:20 |
| User entered 'No (N)' | System | 12 Mar 2021 06:03:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-12T00:03:17-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '341ab3cf-bbb1-4966-bd33-6d2d159c824b' User entered '12 Mar 2021 00:03:17' | System | 12 Mar 2021 06:03:20 |
| | System | 12 Mar 2021 06:03:20 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-19T19:09:38-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '333ec9b0-3bbf-479f-87af-cb7e3b5901cc' | System | 20 Mar 2021 00:09:49 |
| User entered 'No (N)' | System | 20 Mar 2021 00:09:49 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-19T19:09:40-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '333ec9b0-3bbf-479f-87af-cb7e3b5901cc' | System | 20 Mar 2021 00:09:49 |
| User entered 'No (N)' | System | 20 Mar 2021 00:09:49 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-19T19:09:44-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '333ec9b0-3bbf-479f-87af-cb7e3b5901cc' User entered '19 Mar 2021 19:09:44' | System | 20 Mar 2021 00:09:49 |
| | System | 20 Mar 2021 00:09:49 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-28T23:57:17-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3538385-660a-4e85-8445-9db72f4fabed' | System | 29 Mar 2021 04:57:30 |
| User entered 'No (N)' | System | 29 Mar 2021 04:57:30 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-28T23:57:24-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3538385-660a-4e85-8445-9db72f4fabed' | System | 29 Mar 2021 04:57:30 |
| User entered 'No (N)' | System | 29 Mar 2021 04:57:30 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-28T23:57:28-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'a3538385-660a-4e85-8445-9db72f4fabed' User entered '28 Mar 2021 23:57:28' | System | 29 Mar 2021 04:57:30 |
| | System | 29 Mar 2021 04:57:30 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-03T22:26:03-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7accf043-3516-42b0-afaa-86bc55555757' | System | 04 Apr 2021 03:26:18 |
| User entered 'No (N)' | System | 04 Apr 2021 03:26:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-03T22:26:06-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7accf043-3516-42b0-afaa-86bc55555757' | System | 04 Apr 2021 03:26:18 |
| User entered 'No (N)' | System | 04 Apr 2021 03:26:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-03T22:26:11-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '7accf043-3516-42b0-afaa-86bc55555757' | System | 04 Apr 2021 03:26:18 |
| User entered '03 Apr 2021 22:26:11' | System | 04 Apr 2021 03:26:18 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-09T11:18:37-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '17e52d6c-4283-4eef-8de9-12709567ebbe' User entered 'No (N)' | System | 09 Apr 2021 16:19:44 |
| | System | 09 Apr 2021 16:19:44 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-09T11:18:40-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '17e52d6c-4283-4eef-8de9-12709567ebbe' User entered 'No (N)' | System | 09 Apr 2021 16:19:44 |
| | System | 09 Apr 2021 16:19:44 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-09T11:18:44-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '17e52d6c-4283-4eef-8de9-12709567ebbe' User entered '09 Apr 2021 11:18:44' | System | 09 Apr 2021 16:19:44 |
| | System | 09 Apr 2021 16:19:44 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-16T22:23:24-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ee6e9fc0-e12d-4694-8051-73c637af39ed' | System | 17 Apr 2021 03:23:35 |
| User entered 'No (N)' | System | 17 Apr 2021 03:23:35 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-16T22:23:27-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ee6e9fc0-e12d-4694-8051-73c637af39ed' | System | 17 Apr 2021 03:23:35 |
| User entered 'No (N)' | System | 17 Apr 2021 03:23:35 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-16T22:23:31-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'ee6e9fc0-e12d-4694-8051-73c637af39ed' | System | 17 Apr 2021 03:23:35 |
| User entered '16 Apr 2021 22:23:31' | System | 17 Apr 2021 03:23:35 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-23T15:19:15-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b9327547-762d-4013-ac6e-ee7256e16476' | System | 23 Apr 2021 20:19:26 |
| User entered 'No (N)' | System | 23 Apr 2021 20:19:26 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-23T15:19:19-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b9327547-762d-4013-ac6e-ee7256e16476' | System | 23 Apr 2021 20:19:26 |
| User entered 'No (N)' | System | 23 Apr 2021 20:19:26 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-23T15:19:23-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: 'b9327547-762d-4013-ac6e-ee7256e16476' | System | 23 Apr 2021 20:19:26 |
| User entered '23 Apr 2021 15:19:23' | System | 23 Apr 2021 20:19:26 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-30T01:53:40-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '6993b6c5-e41d-45f2-bf8f-b926cd34d00d' User entered 'No (N)' | System | 30 Apr 2021 06:54:00 |
| | System | 30 Apr 2021 06:54:00 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

Have you been exposed to someone with 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 (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-30T01:53:45-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '6993b6c5-e41d-45f2-bf8f-b926cd34d00d' User entered 'No (N)' | System | 30 Apr 2021 06:54:00 |
| | System | 30 Apr 2021 06:54:00 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-04-30T01:53:57-05:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '6993b6c5-e41d-45f2-bf8f-b926cd34d00d' User entered '30 Apr 2021 01:53:57' | System | 30 Apr 2021 06:54:00 |
| | System | 30 Apr 2021 06:54:00 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 13:38:11 |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:03:00

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 13:38:11 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 19 Nov 2020 13:38:11 |

US3092021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:00

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-03T09:02:36-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0a01d698-17a2-46c8-8270-065e91a996ea' User entered 'No (N)' | System | 03 Mar 2021 15:02:52 |
| | System | 03 Mar 2021 15:02:52 |

US3092021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:03:00

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 23:39:24 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7CA732A-E867-440D-BE72-DE213430CAC6)', Time: '2021-03-03T09:02:47-06:00', User OID: 'PatientReportedOutcome (US3092021)', ODM File OID: '0a01d698-17a2-46c8-8270-065e91a996ea' User entered '03 Mar 2021 09:02:47' | System | 03 Mar 2021 15:02:52 |
| | System | 03 Mar 2021 15:02:52 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) destiny robinson (b) (4) | 29 Oct 2020 20:57:06 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 05 Nov 2020 01:11:08 |
| User entered '29 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Nov 2020 22:45:47 |
| Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'SAFETY CALL ATTEMPT CONFIRM AND CORRECT' (Site from System). | | 03 Nov 2020 22:42:55 |
| User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 03 Nov 2020 22:42:13 |
| User entered '03 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Nov 2020 22:42:13 |
| User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 29 Oct 2020 21:04:33 |
| Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System). | System | 29 Oct 2020 21:04:33 |
| User entered '29 Oct 2020' reason for change: Data Entry Error | destiny robinson (b) (4) (b) (4) | 29 Oct 2020 21:04:33 |
| User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 29 Oct 2020 20:57:21 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'Future date has been entered. Please correct.' (Site from System). | System | 29 Oct 2020 20:57:21 |
| User entered '17 Oct 2020' reason for change: Data Entry Error | destiny robinson (b) (4) | 29 Oct 2020 20:57:21 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 29 Oct 2020 20:57:13 |
| User entered '30 Oct 2020' reason for change: Data Entry Error | destiny robinson (b) (4) | 29 Oct 2020 20:57:13 |
| User entered '28 Oct 2020' | destiny robinson (b) (4) | 29 Oct 2020 20:57:06 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) destiny robinson (b) (4) (b) (4) | 29 Oct 2020 20:57:06 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | destiny robinson (b) (4) | 29 Oct 2020 20:57:06 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 29 Oct 2020 23:15:08 |

US3092021

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 23:26:46 |
| User entered 'I' | System | 29 Oct 2020 23:15:08 |

US3092021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 02 Dec 2020 23:06:13 |

US3092021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '2 Dec 2020' | Catina Adams (b) (4) | 02 Dec 2020 23:06:13 |

US3092021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Contact Made (CONTACT MADE)' | Catina Adams (b) (4) | 02 Dec 2020 23:06:13 |

US3092021

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Catina Adams (b) (4) | 02 Dec 2020 23:06:13 |

US3092021

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 02 Dec 2020 23:06:21 |

US3092021

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'I' | System | 02 Dec 2020 23:06:21 |

US3092021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 05 Jan 2021 18:44:39 |

US3092021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Jan 2021 06:12:30 |
| Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'first attempt was in window. last date of contact was out of window. Date correct. ' (Site from System). | (b) (4), (b) (6) | 05 Jan 2021 19:20:05 |
| User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System). | System | 05 Jan 2021 18:44:39 |
| User entered '05 Jan 2021' | (b) (4), (b) (6) | 05 Jan 2021 18:44:39 |

US3092021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 05 Jan 2021 18:44:39 |

US3092021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Jan 2021 18:44:39 |

US3092021

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 05 Jan 2021 19:20:10 |

US3092021

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'I' | System | 05 Jan 2021 19:20:10 |

US3092021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 18:54:08 |

US3092021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '29 Jan 2021' | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 18:54:08 |

US3092021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 18:54:08 |

US3092021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 18:54:08 |

US3092021

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 29 Jan 2021 18:54:23 |

US3092021

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'I' | System | 29 Jan 2021 18:54:23 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:20:55 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:20:55 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:20:55 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'VISIT4' | System | 26 Feb 2021 23:20:55 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '13:10' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered '25 Feb 2021 13:10' | System | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '97.5' F | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '78' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'bpm' | System | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'breaths/min' | System | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '129' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'mmHg' | System | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '73' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'mmHg' | System | 30 Mar 2021 21:59:10 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| | | |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| | | |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Was the physical examination performed?

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:26 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | | 30 Mar 2021 21:59:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:54:20 |
| User entered 'No (N)' reason for change: Data Entry Error | | 08 Mar 2021 16:54:20 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:21:54 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 21:59:26 |
| User entered '25 Feb 2021' reason for change: Data Entry Error | | 30 Mar 2021 21:59:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:54:20 |
| User entered empty; reason for change Data Entry Error | | 08 Mar 2021 16:54:20 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:21:54 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:50:07 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:50:07 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '13:48' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:50:07 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered '25 Feb 2021 13:48' | System | 08 Mar 2021 16:50:07 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:21:58 |

US3092021

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 15:22:40 |
| User entered 'I' | System | 26 Feb 2021 23:21:58 |

US3092021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:39:08 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 19:34:46 |

US3092021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:39:08 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered '29 Mar 2021' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 19:34:46 |

US3092021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:39:08 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 19:34:46 |

US3092021

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:39:08 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 19:34:46 |

US3092021

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:39:08 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 31 Mar 2021 16:31:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 30 Mar 2021 19:34:51 |

US3092021

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 02:39:08 |
| User entered 'I' | System | 30 Mar 2021 19:34:51 |

US3092021

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Apr 2021 16:25:47 |

US3092021

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| User entered '27 Apr 2021' | (b) (4) (b) (4), (b) (6) | 28 Apr 2021 16:25:47 |

US3092021

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 28 Apr 2021 16:25:47 |

US3092021

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Apr 2021 16:25:47 |

US3092021

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Apr 2021 16:26:06 |

US3092021

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Apr 2021 16:26:06 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:00

[Date of Contact](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| | (b) (4), (b) (6) | 07 Jan 2021 08:24:18 |
| Comment added 'Data was entered for incorrect subject number.' | Marissa Cervenka (b) (4) | 06 Jan 2021 23:42:56 |
| | (b) (4) | |
| Query 'Data is required. Please complete.' answered with 'Data was entered for incorrect subject number.(U2092130)' (Site from System). | Marissa Cervenka (b) (4) | 06 Jan 2021 23:29:18 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Jan 2021 23:24:11 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:24:11 |
| | (b) (4) | |
| User entered '4 Jan 2021' | Marissa Cervenka (b) (4) | 05 Jan 2021 00:50:56 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:00

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 08:24:20 |
| Comment added 'Data was entered for incorrect subject number.' | Marissa Cervenka (b) (4) | 06 Jan 2021 23:43:56 |
| Query 'Data is required. Please complete.' answered with 'Data was entered for incorrect subject number.(U2092130)' (Site from System). | (b) (4) Marissa Cervenka (b) (4) | 06 Jan 2021 23:29:21 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Jan 2021 23:24:11 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:24:11 |
| User entered '08:35' | Marissa Cervenka (b) (4) | 05 Jan 2021 00:50:56 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:00

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User entered empty. | System | 06 Jan 2021 23:24:11 |
| User entered '4 Jan 2021 08:35' | System | 05 Jan 2021 00:50:56 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:00

[Type of Contact](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Comment added 'Data was entered for incorrect subject number.' | (b) (4), (b) (6) | 07 Jan 2021 08:24:22 |
| Query 'Data is required. Please complete.' answered with 'Data was entered for incorrect subject number.(U2092130)' (Site from System). | Marissa Cervenka (b) (4) | 06 Jan 2021 23:44:04 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:29:25 |
| User entered 'Safety Call (Safety Call)' | System | 06 Jan 2021 23:24:11 |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:24:11 |
| | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 00:50:56 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:03:00

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 08:24:24 |
| Query 'Data is required. Please complete.' answered with 'Data was entered for incorrect subject number.(U2092130)' (Site from System). | Marissa Cervenka (b) (4) (b) (4) | 06 Jan 2021 23:29:29 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Jan 2021 23:24:11 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) (b) (4) | 06 Jan 2021 23:24:11 |
| User entered 'Yes (Y)' | Marissa Cervenka (b) (4) (b) (4) | 05 Jan 2021 00:50:56 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Day 1 (Day 1)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Date](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 08:24:29 |
| Query 'Data is required. Please complete.' answered with 'Data was entered for incorrect subject number.(U2092130)' (Site from System). | Marissa Cervenka (b) (4) (b) (4) | 06 Jan 2021 23:31:04 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Jan 2021 23:30:58 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) (b) (4) | 06 Jan 2021 23:30:58 |
| User entered '3 Jan 2021' | Marissa Cervenka (b) (4) (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User entered empty. | System | 06 Jan 2021 23:30:58 |
| User entered '%' | System | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

Temperature

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered '100.5' F | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Chills](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Moderate (Moderate)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Cough](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Severe (Severe)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Severe (Severe)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Body Aches](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Severe (Severe)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Headache](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Moderate (Moderate)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Mild (Mild)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Mild (Mild)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Nausea](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:03:00

[Sore Throat](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:30:58 |
| User entered 'Severe (Severe)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:01:30 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Day 2 (Day 2)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Date](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 08:24:34 |
| Query 'Data is required. Please complete.' answered with 'Data was entered for incorrect subject number.(U2092130)' (Site from System). | Marissa Cervenka (b) (4) (b) (4) | 06 Jan 2021 23:32:48 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Jan 2021 23:32:40 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) (b) (4) | 06 Jan 2021 23:32:40 |
| User entered '4 Jan 2021' | Marissa Cervenka (b) (4) (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '0' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered '99' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User entered empty. | System | 06 Jan 2021 23:32:40 |
| User entered '%' | System | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

Temperature

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered '98.8' F | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Chills](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Moderate (Moderate)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Cough](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Severe (Severe)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Severe (Severe)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Body Aches](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Severe (Severe)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Headache](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Mild (Mild)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Mild (Mild)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Mild (Mild)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Nausea](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Vomiting](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |
| | (b) (4) | |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Diarrhea](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'None (None)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:03:00

[Sore Throat](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:32:40 |
| User entered 'Severe (Severe)' | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:44 |

US3092021

Folder: Covid-19 Assessment 04 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:03:00

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:49:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:37:57 |
| User entered 'Yes (Y)' | | 13 Jan 2021 03:43:05 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:03:00

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |
| | | |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:03:00

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:03:00

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |
| | | |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:03:00

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:03:00

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |
| | | |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:03:00

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:03:00

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |
| | | |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:03:00

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:03:00

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |
| | | |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:03:00

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:03:00

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |
| | | |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:03:00

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:03:00

[Visit](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |
| | | |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:03:00

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:39:09 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:38 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:38 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:38 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 22 Jan 2021 17:38:38 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:44 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:49 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:49 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:03:00

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:54 |

US3092021

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:03:00

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Jan 2021 17:38:54 |

US3092021

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:05:03 |

US3092021

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:05:03 |

US3092021

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:05:03 |

US3092021

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

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'UNBLND_DECIDE' | System | 28 Jan 2021 22:05:03 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 04:32:24 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 04:32:24 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '1' | System | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Unblinding

Generated On: 09 Jun 2021 15:03:00

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'I' | System | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

Height

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System). | (b) (4) | 28 Jan 2021 22:09:44 |
| Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System). | System | 28 Jan 2021 22:09:44 |
| User entered '187.96' cm reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Jan 2021 22:09:44 |
| User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System). | System | 28 Jan 2021 22:09:05 |
| User entered '187.96' in | (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '289.8' lb | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '37.28592' | System | 28 Jan 2021 22:09:44 |
| User entered '5.77933' | System | 28 Jan 2021 22:09:05 |
| DataPoint set to visible. | System | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

Height

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System). | (b) (4) | 28 Jan 2021 22:09:44 |
| Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System). | System | 28 Jan 2021 22:09:44 |
| User entered '187.96' cm reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Jan 2021 22:09:44 |
| User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System). | System | 28 Jan 2021 22:09:05 |
| User entered '187.96' in | (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '289.8' lb | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '37.28592' | System | 28 Jan 2021 22:09:44 |
| User entered '5.77933' | System | 28 Jan 2021 22:09:05 |
| DataPoint set to visible. | System | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '13:35' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '28 Jan 2021 13:35' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '97.7' F | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '78' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'bpm' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'breaths/min' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '139' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '89' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

Height

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System). | (b) (4) | 28 Jan 2021 22:09:44 |
| Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System). | System | 28 Jan 2021 22:09:44 |
| User entered '187.96' cm reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Jan 2021 22:09:44 |
| User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System). | System | 28 Jan 2021 22:09:05 |
| User entered '187.96' in | (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '289.8' lb | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:03:00

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '37.28592' | System | 28 Jan 2021 22:09:44 |
| User entered '5.77933' | System | 28 Jan 2021 22:09:05 |
| DataPoint set to visible. | System | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:40' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '28 Jan 2021 14:40' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '97.7' F | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '74' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'bpm' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'breaths/min' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '131' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '81' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 28 Jan 2021 22:09:05 |

US3092021

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:06 |

US3092021

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:06 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mRNA-1273' | System | 28 Jan 2021 22:10:33 |
| DataPoint set to visible. | System | 28 Jan 2021 22:06:50 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:08' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '28 Jan 2021 14:08' | System | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'ONCE' | System | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'INTRAMUSCULAR' | System | 28 Jan 2021 22:10:33 |

US3092021

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:52 |

US3092021

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:10:52 |

US3092021

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:05' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:11:36 |
| User entered '14:08' | | 28 Jan 2021 22:10:52 |

US3092021

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '28 Jan 2021 14:05' | System | 28 Jan 2021 22:11:36 |
| User entered '28 Jan 2021 14:08' | System | 28 Jan 2021 22:10:52 |

US3092021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:11:25 |

US3092021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '28 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:11:25 |

US3092021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:00

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '14:02' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:11:25 |

US3092021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '28 Jan 2021 14:02' | System | 28 Jan 2021 22:11:25 |

US3092021

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

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 22:11:44 |

US3092021

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

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '1' | System | 28 Jan 2021 22:11:44 |

US3092021

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 01:13:14 |

US3092021

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '04 Feb 2021' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 01:13:14 |

US3092021

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 01:13:14 |

US3092021

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 01:13:14 |

US3092021

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 01:14:18 |

US3092021

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'I' | System | 05 Feb 2021 01:14:18 |

US3092021

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '1' | System | 05 Feb 2021 01:14:18 |
| DataPoint set to visible. | System | 05 Feb 2021 01:14:18 |

US3092021

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:23:14 |

US3092021

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:23:14 |

US3092021

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:23:14 |

US3092021

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'OLD29' | System | 26 Feb 2021 23:23:14 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '13:10' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '25 Feb 2021 13:10' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '97.5' F | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '78' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'bpm' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'breaths/min' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '129' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '73' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '14:24' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '25 Feb 2021 14:24' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '97.8' F | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '78' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'bpm' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'breaths/min' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '132' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '75' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 26 Feb 2021 23:25:25 |

US3092021

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:36 |

US3092021

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:25:36 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

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) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mRNA-1273' | System | 26 Feb 2021 23:26:03 |
| DataPoint set to visible. | System | 05 Feb 2021 01:14:18 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '25 Feb 2021' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered '13:52' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '25 Feb 2021 13:52' | System | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'ONCE' | System | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:03:00

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'INTRAMUSCULAR' | System | 26 Feb 2021 23:26:03 |

US3092021

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 07 Mar 2021 18:17:14 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Feb 2021 23:27:58 |

US3092021

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'I' | System | 26 Feb 2021 23:27:58 |

US3092021

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:52:28 |

US3092021

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '05 Mar 2021' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:52:28 |

US3092021

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:52:28 |

US3092021

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:03:00

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:52:28 |

US3092021

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 16:52:33 |

US3092021

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:03:00

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'I' | System | 08 Mar 2021 16:52:33 |

US3092021

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:21 |

US3092021

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:21 |

US3092021

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:21 |

US3092021

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:03:00

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'OLD57' | System | 26 Mar 2021 22:59:21 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '13:25' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '26 Mar 2021 13:25' | System | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '98.2' F | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '79' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'bpm' | System | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'breaths/min' | System | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '140' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '95' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered 'mmHg' | System | 26 Mar 2021 22:59:56 |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| | | |

US3092021

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:03:00

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| | | |

US3092021

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 23:00:11 |

US3092021

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:03:00

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 23:00:11 |

US3092021

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 23:00:34 |

US3092021

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '26 Mar 2021' | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 23:00:34 |

US3092021

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 00:59:32 |
| User entered '13:57' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 26 Mar 2021 23:00:58 |
| User entered '13:25' | | 26 Mar 2021 23:00:34 |

US3092021

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:03:00

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 16:21:36 |
| User entered '26 Mar 2021 13:57' | System | 26 Mar 2021 23:00:58 |
| User entered '26 Mar 2021 13:25' | System | 26 Mar 2021 23:00:34 |

US3092021

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:03:00

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:50:49 |
| User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 180 & 187, '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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | | 12 Apr 2021 06:30:18 |
| Query 'Per DM CLR: Per Safety Follow Up Diary Day 180 & 187, '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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'For Day 180 (29JAN2021), subject returned call on 01FEB2021 and stated that he saw his primary care physician for a routine follow-up. This was NOT an AE or MAAE. For Day 187 (06FEB2021), the subject was called on 08FEB2021 and stated that his contact with a healthcare provider was for the previously reported routine follow-up visit with his primary care physician (previously captured on his safety follow up diary Day 180). This is also NOT an AE or MAAE. In conclusion, none of the questions to which the subject answered yes on the safety follow up diary qualify for a MAAE. ' (Site from DM). | (b) (4), (b) (6) | 10 Apr 2021 15:53:59 |

US3092021

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:03:00

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 180 & 187, '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. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 25 Mar 2021 03:41:29 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | Marissa Cervenka (b) (4) | 06 Jan 2021 23:47:57 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | System | 06 Jan 2021 23:41:29 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Jan 2021 23:41:29 |
| User entered empty; reason for change Data Entry Error | Marissa Cervenka (b) (4) | 06 Jan 2021 23:41:29 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| User entered 'No (N)' | Marissa Cervenka (b) (4) | 06 Jan 2021 23:41:18 |
| | System | 06 Jan 2021 23:41:18 |
| | Marissa Cervenka (b) (4) | 06 Jan 2021 23:41:18 |
| | (b) (4) | |
| | Marissa Cervenka (b) (4) | 05 Jan 2021 01:02:55 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:05:18 |
| | (b) (4) | |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:35 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:27 |
| User entered 'USA-US086-2021-mRNA-1273-P301000002' | System | 07 Jan 2021 17:31:22 |
| User entered 'New' | (b) (4), (b) (6) | 07 Jan 2021 17:31:22 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:37 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0. | Coder Import (b) (4) | 13 Mar 2021 14:31:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 13 Mar 2021 14:31:43 |
| Data point term sent to Coder | System | 10 Mar 2021 21:54:18 |
| Coding entries removed. | Vicki Martinez (b) (4) | 10 Mar 2021 21:53:59 |
| User entered 'COPD EXACEBRATION' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 10 Mar 2021 21:53:59 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0. | Coder Import (b) (4) | 07 Jan 2021 15:50:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 07 Jan 2021 15:50:41 |
| Data point term sent to Coder | System | 07 Jan 2021 15:33:21 |
| User entered 'COPD EXACORBATION' | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:48 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User closed query 'Per DM CLR: Please review if this was medically-attended as hospitalization was recorded for this event. Update entry. Else, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 10 Feb 2021 14:04:00 |
| Query 'Per DM CLR: Please review if this was medically-attended as hospitalization was recorded for this event. Update entry. Else, clarify.' answered with 'Updated' (Site from DM). | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:29:42 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:29:22 |
| User opened query 'Per DM CLR: Please review if this was medically-attended as hospitalization was recorded for this event. Update entry. Else, clarify.' (Site from DM). | (b) (4), (b) (6) | 31 Jan 2021 13:12:51 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:50 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:52 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:54 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '15 Nov 2020' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:55 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:57 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:21:59 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '17 Nov 2020' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:00 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

Severity

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:05 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User closed query 'PV Query: Since the subject was hospitalized for the event of COPD exacerbation, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:38:42 |
| Query 'PV Query: Since the subject was hospitalized for the event of COPD exacerbation, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' answered with 'Updated' (Site from Safety). | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:30:41 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:30:27 |
| User opened query 'PV Query: Since the subject was hospitalized for the event of COPD exacerbation, appropriate CTCAE grade should be grade 3 instead of grade 1. Please update the event severity as such. If the severity is to remain grade 1, please clarify/explain.' (Site from Safety). | (b) (4), (b) (6) | 12 Jan 2021 15:25:58 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:06 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:08 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:10 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:11 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User closed query 'Per CDM, re-query: Please note that Admitted to ICU? is still missing. Kindly update as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 07:41:16 |
| Query 'Per CDM, re-query: Please note that Admitted to ICU? is still missing. Kindly update as appropriate.' answered with 'updated ' (Site from DM). | destiny robinson (b) (4) (b) (4) | 10 Feb 2021 15:49:36 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 08 Jan 2021 08:04:04 |
| User opened query 'Per CDM, re-query: Please note that Admitted to ICU? is still missing. Kindly update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 08 Jan 2021 08:04:02 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Dates have been updated' (Site from System). | (b) (4), (b) (6) | 07 Jan 2021 15:38:42 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 07 Jan 2021 15:33:08 |
| User entered 'I' | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:13 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '15 Nov 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:38:22 |
| User entered empty. | | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:15 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '17 Nov 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:38:22 |
| User entered empty. | | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:17 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'No (N)' reason for change: Data Entry Error | destiny robinson (b) (4) | 10 Feb 2021 15:49:40 |
| User entered empty. | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:18 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:20 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:21 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:23 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:26 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User closed query 'PV Query Urgent: Please update causality assessment to related or not related for the event and study procedure as soon as possible.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:38:38 |
| Query 'PV Query Urgent: Please update causality assessment to related or not related for the event and study procedure as soon as possible.' answered with 'Updated' (Site from Safety). | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:33:48 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:29:22 |
| User opened query 'PV Query Urgent: Please update causality assessment to related or not related for the event and study procedure as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 12 Jan 2021 15:24:44 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:27 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User closed query 'PV Query Urgent: Please update causality assessment to related or not related for the event and study procedure as soon as possible.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:38:35 |
| Query 'PV Query Urgent: Please update causality assessment to related or not related for the event and study procedure as soon as possible.' answered with 'Updated' (Site from Safety). | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:33:42 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:29:22 |
| User opened query 'PV Query Urgent: Please update causality assessment to related or not related for the event and study procedure as soon as possible.' (Site from Safety). | (b) (4), (b) (6) | 12 Jan 2021 15:24:55 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:29 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

None

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Mar 2021 19:24:34 |
| Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'MEDICAL RECORDS REQUEST STILL PENDING. PER SUBJECT NO MEDICATIONS WERE PROSCRIBED AND ONLY A COVID TEST WAS DONE.' (Site from DM). | (b) (4), (b) (6) | 11 Mar 2021 17:25:26 |
| User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 02:25:53 |
| User entered 'I' | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:32 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:34 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:35 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:37 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

US3092021

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User closed query 'PV Query: Please leave query open until information is received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 28 Apr 2021 20:04:47 |
| Query 'PV Query: Please leave query open until information is received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Emailed relevant laboratory and diagnostic results.' (Site from Safety). | (b) (4), (b) (6) | 28 Apr 2021 18:48:25 |
| User opened query 'PV Query: Please leave query open until information is received. Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). | (b) (4), (b) (6) | 12 Apr 2021 19:30:19 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). | (b) (4), (b) (6) | 12 Apr 2021 18:38:16 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 12 Apr 2021 18:38:12 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Medical records have been requested three times on the 23/NOV/2020, 29/JAN/2021 and 09/APR/2021 and are still waiting to be received. ' (Site from Safety). | (b) (4), (b) (6) | 09 Apr 2021 20:39:16 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Per subject on 01FEB2021, there was no medical intervention and/or surgical treatments. Subject also states that there were no procedures or concomitant medications given.' (Site from Safety). | (b) (4), (b) (6) | 09 Apr 2021 20:12:04 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 16:22:50 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 20:42:02 |

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 20:39:04 |
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety). | (b) (4), (b) (6) | 02 Apr 2021 20:38:52 |
| 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) | 02 Apr 2021 20:38:22 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 12 Mar 2021 19:45:53 |
| 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) | 12 Mar 2021 19:45:49 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'MEDICAL RECORDS HAVE BEEN REQUESTED MULTIPLE TIMES. PER SUBJECT NO MEDICATIONS WERE GIVEN AND THE ONLY MEDICAL INTERVENTION DONE WAS A COVID TEST' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 17:27:27 |

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Folder: Adverse Events

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'MEDICAL RECORDS HAVE BEEN REQUESTED FOUR TIMES AND DATA WILL BE UPDATED IF THERE ARE ANY CHANGES IN STATUS' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 17:26:23 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 12 Jan 2021 15:25:28 |
| 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) | 12 Jan 2021 15:25:17 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 07 Jan 2021 15:38:22 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System). | System | 07 Jan 2021 15:38:22 |
| User entered 'subject was hospitalized per diagnosed with COPD exacerbation outbreak.' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Jan 2021 15:38:22 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System). | System | 07 Jan 2021 15:33:08 |
| User entered empty. | (b) (4), (b) (6) | 07 Jan 2021 15:33:08 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Jan 2021 15:33:08 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 04 Feb 2021 23:29:22 |
| User entered '0' | System | 07 Jan 2021 15:33:08 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:03:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 10 Feb 2021 15:49:40 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:03:00

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:50:49 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per CDM, re-query: Response " Subject took Hydrocodone/tylenol 10-325mg" is noted; however, the corresponding medication has not been added to the Con Med eCRF. Please update as appropriate, else clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 10:04:13 |
| Query 'Per CDM, re-query: Response " Subject took Hydrocodone/tylenol 10-325mg" is noted; however, the corresponding medication has not been added to the Con Med eCRF. Please update as appropriate, else clarify. ' answered with 'Updated' (Site from DM). | Catina Adams (b) (4) (b) (4) | 09 Dec 2020 19:57:59 |
| User opened query 'Per CDM, re-query: Response " Subject took Hydrocodone/tylenol 10-325mg" is noted; however, the corresponding medication has not been added to the Con Med eCRF. Please update as appropriate, else clarify. ' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 13:26:14 |
| User closed query 'Per CDM: Per Diary Dose 1 Day 5, Day 6, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Con-med recorded that matches this information in the Con-Med eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 13:26:14 |
| Query 'Per CDM: Per Diary Dose 1 Day 5, Day 6, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Con-med recorded that matches this information in the Con-Med eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' answered with 'Subject took Hydrocodone/tylenol 10-325mg' (Site from DM). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:26:32 |
| User opened query 'Per CDM: Per Diary Dose 1 Day 5, Day 6, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Con-med recorded that matches this information in the Con-Med eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 04:50:52 |

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:03:00

Were any prior/concomitant medications and/or vaccinations taken?

| Audit | User | Time (GMT) |
|------------------------|-----------------------------------|----------------------|
| User entered 'Yes (Y)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 13:31:38 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 14 Aug 2020 10:38:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 10:38:17 |
| Data point term sent to Coder | System | 10 Aug 2020 14:16:40 |
| User entered 'Novolog' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:16:29 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'Diabetes' | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per CDM, per DM CLR re-query: Update noted; however, please also update the dose unit to provide the actual dose instead of number of injections as per the DM CLR query. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Nov 2020 12:22:35 |
| Query 'Per CDM, per DM CLR re-query: Update noted; however, please also update the dose unit to provide the actual dose instead of number of injections as per the DM CLR query. Thank you.' answered with '100 units. Updated' (Site from DM). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:15:45 |
| User opened query 'Per CDM, per DM CLR re-query: Update noted; however, please also update the dose unit to provide the actual dose instead of number of injections as per the DM CLR query. Thank you.' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 12:06:15 |
| User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection, as the dose may vary. Please update as appropriate or provide clarification.' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 12:05:02 |
| Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection, as the dose may vary. Please update as appropriate or provide clarification.' answered with 'documented' (Site from DM). | destiny robinson (b) (4) (b) (4) | 19 Oct 2020 18:27:00 |
| User entered '100' reason for change: Data Entry Error | destiny robinson (b) (4) (b) (4) | 19 Oct 2020 18:26:51 |
| User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection, as the dose may vary. Please update as appropriate or provide clarification.' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 12:45:41 |
| User entered '1' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:52:33 |
| User entered '100' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:16:29 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System). | (b) (4) System | 19 Oct 2020 18:27:52 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | destiny robinson (b) (4) (b) (4) | 19 Oct 2020 18:27:52 |
| User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System). | System | 19 Oct 2020 18:26:51 |
| User entered 'IU (IU)' reason for change: Data Entry Error | destiny robinson (b) (4) (b) (4) | 19 Oct 2020 18:26:51 |
| User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM). | (b) (4), (b) (6) | 19 Oct 2020 10:03:08 |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' answered with 'Updated' (Site from DM). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:52:38 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 22 Sep 2020 19:52:33 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Sep 2020 19:52:33 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:52:33 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 22 Sep 2020 19:51:16 |
| User entered empty; reason for change Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:51:16 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:50:39 |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM). | (b) (4), (b) (6) | 03 Sep 2020 08:08:00 |
| User entered 'mg (mg)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:16:29 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'units' reason for change: Data Entry Error | Catina Adams (b) (4) | 23 Oct 2020 16:13:24 |
| | (b) (4) | |
| User entered 'Injection' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 19:52:33 |
| | (b) (4) | |
| User entered 'U/ML' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 19:50:39 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | |
| | System | 22 Sep 2020 19:50:39 |
| User entered 'UN UNK 2008' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 19:50:39 |
| | (b) (4) | |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 10 Aug 2020 14:16:29 |
| User entered ' 2008' (non-conformant). | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '0' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 19:50:39 |
| | (b) (4) | |
| User entered '1' | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:16:29 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:16:29 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:16:29 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 10 Aug 2020 14:16:29 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DEGLUDEC, PRODUCTSYNONYM: TRESIBA - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 10 Aug 2020 14:20:15 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 14:20:15 |
| Data point term sent to Coder | System | 10 Aug 2020 14:18:43 |
| User entered 'Tresiba' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:18:04 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'Diabetes' | Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per CDM, per DM CLR re-query: Response 'units per ML' noted; however, please also update the dose unit to reflect your response instead of number of injections. Thank you. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Nov 2020 12:23:13 |
| Query 'Per CDM, per DM CLR re-query: Response 'units per ML' noted; however, please also update the dose unit to reflect your response instead of number of injections. Thank you. ' answered with '200 units daily' (Site from DM). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:31:16 |
| User opened query 'Per CDM, per DM CLR re-query: Response 'units per ML' noted; however, please also update the dose unit to reflect your response instead of number of injections. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 12:07:51 |
| User closed query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection, as the dose may vary. Please update as appropriate or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 12:07:51 |
| Query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection, as the dose may vary. Please update as appropriate or provide clarification. ' answered with 'units per ML ' (Site from DM). | destiny robinson (b) (4) (b) (4) | 19 Oct 2020 18:29:08 |
| User entered '200' reason for change: Data Entry Error | destiny robinson (b) (4) (b) (4) | 19 Oct 2020 18:28:56 |
| User opened query 'Per DM CLR: Please review and update to provide the actual dose rather than the number of injection, as the dose may vary. Please update as appropriate or provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 12:48:26 |
| User entered '1' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:53:33 |
| User entered '200' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:18:04 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 10:03:30 |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' answered with 'Updated' (Site from DM). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:54:38 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:53:33 |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 03 Sep 2020 08:08:13 |
| User entered 'mL (mL)' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:18:04 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'units' reason for change: Data Entry Error | Catina Adams (b) (4) | 23 Oct 2020 16:31:27 |
| | (b) (4) | |
| User entered 'Injection' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 22 Sep 2020 19:53:33 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Frequency](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'once daily (QD)' reason for change: | Catina Adams (b) (4) | 23 Oct 2020 16:31:27 |
| Data Entry Error | (b) (4) | |
| User entered 'unknown (UNKNOWN)' | Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:18:04 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'I' | Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:18:04 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 23 Oct 2020 16:31:27 |
| User entered empty. | System | 10 Aug 2020 14:18:04 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 23 Oct 2020 16:31:27 |
| User entered empty. | System | 10 Aug 2020 14:18:04 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 23 Oct 2020 16:31:27 |
| User entered empty. | System | 10 Aug 2020 14:18:04 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 10 Aug 2020 14:22:21 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 14:22:21 |
| Data point term sent to Coder | System | 10 Aug 2020 14:20:45 |
| User entered 'Losartan' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:19:52 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'Hypertension' | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per DM CLR: Please review Dose listed for this medication as this is mono-component Drug. Please correct the dosage or provide explanation for this dosage. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 10:03:59 |
| Query 'Per DM CLR: Please review Dose listed for this medication as this is mono-component Drug. Please correct the dosage or provide explanation for this dosage. ' answered with 'Updated' (Site from DM). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:56:18 |
| User entered '1' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 19:56:07 |
| User opened query 'Per DM CLR: Please review Dose listed for this medication as this is mono-component Drug. Please correct the dosage or provide explanation for this dosage. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Sep 2020 08:08:30 |
| User entered '100/25' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:19:52 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'tablet (TABLET)' reason for change: Data Entry Error | (b) (4) Heather Jimenez (b) (4) | 22 Sep 2020 19:56:07 |
| User entered 'mg (mg)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (ORAL)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'I' | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:19:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:19:52 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:19:52 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 10 Aug 2020 14:19:52 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 14 Aug 2020 10:30:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 10:30:28 |
| Data point term sent to Coder | System | 10 Aug 2020 14:21:46 |
| User entered 'Omeprozole' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:21:25 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Gastroesophageal reflux disease' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '20' | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'mg (mg)' | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Oral (ORAL)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'I' | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:21:25 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:21:25 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:21:25 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 10 Aug 2020 14:21:25 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 10 Aug 2020 18:06:13 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Aug 2020 18:06:13 |
| Data point term sent to Coder | System | 10 Aug 2020 14:23:50 |
| User entered 'Atorvastatin' | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:22:53 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Hypecholesterlemia' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '80' | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'mg (mg)' | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'once daily (QD)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'I' | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'Yes (Y)' | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Robert Miranda (b) (4) | 10 Aug 2020 14:22:53 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:22:53 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 10 Aug 2020 14:22:53 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 10 Aug 2020 14:22:53 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

Name of Medication

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: VICODIN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 11 Feb 2021 12:51:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 11 Feb 2021 12:51:51 |
| User closed query 'Per DM CLR: Please update the name of the medication to reflect the actual active ingredient / brand name. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 09:42:29 |
| Data point term sent to Coder | System | 06 Feb 2021 00:52:30 |
| User entered 'HYDROCODNE (vicoden)/TYLENOL' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 06 Feb 2021 00:51:52 |
| Data point term sent to Coder | System | 06 Feb 2021 00:51:29 |
| Query 'Per DM CLR: Please update the name of the medication to reflect the actual active ingredient / brand name. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM). | Heather Jimenez (b) (4) | 06 Feb 2021 00:51:24 |
| User entered 'HYDROCODNE/TYLENOL (Vicoden)' reason for change: Data Entry Error | Heather Jimenez (b) (4) | 06 Feb 2021 00:51:02 |
| Data point term sent to Coder | System | 04 Feb 2021 23:43:09 |
| Coding entries removed. | Heather Jimenez (b) (4) | 04 Feb 2021 23:42:46 |
| User opened query 'Per DM CLR: Please update the name of the medication to reflect the actual active ingredient / brand name. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 08 Jan 2021 15:46:16 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Dec 2020 21:29:51 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Dec 2020 21:29:51 |
| Data point term sent to Coder | System | 09 Dec 2020 19:47:46 |
| User entered 'Hydrocodne/Tylenol' | Catina Adams (b) (4) (b) (4) | 09 Dec 2020 19:47:15 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Per CDM, DM CLR re-query: Thank you for the update; however, please note that the condition is not present on the MH page. Please record the condition and all applicable details and ensure Con Med and MH pages are reconciled. Review and update as appropriate.' (Site from DM). Query 'Per CDM, DM CLR re-query: Thank you for the update; however, please note that the condition is not present on the MH page. Please record the condition and all applicable details and ensure Con Med and MH pages are reconciled. Review and update as appropriate.' answered with 'it has been documented on source. will check edc and update if necessary ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 11 Feb 2021 08:03:33 |
| User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). | destiny robinson (b) (4) (b) (4) | 10 Feb 2021 15:47:56 |
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 09:54:54 |
| User entered 'LEFT KNEE Pain' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Feb 2021 09:54:53 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM). | Heather Jimenez (b) (4) (b) (4) | 06 Feb 2021 00:51:18 |
| User entered 'LEFT KNEE Arthroplasty' reason for change: Data Entry Error | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:42:56 |
| | Heather Jimenez (b) (4) (b) (4) | 04 Feb 2021 23:42:46 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 08 Jan 2021 15:46:33 |
| User entered 'Left Knee Replacement' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '10-325' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'mg (mg)' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'UN UNK 2011' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '0' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered empty. | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered 'No (N)' | Catina Adams (b) (4) | 09 Dec 2020 19:47:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Dec 2020 19:47:15 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Dec 2020 19:47:15 |

US3092021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:03:00

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 09 Dec 2020 19:47:15 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:03:00

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6) | 14 Apr 2021 16:15:31 |
| DataPoint Verified. | | 14 Apr 2021 16:14:18 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:04:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Robert Miranda (b) (4) | 10 Aug 2020 14:23:36 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 07:51:52 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 20:05:26 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Aug 2020 14:25:00 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:25:00 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:51:47 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:05:40 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:05:30 |
| User entered 'Diabetese Type 2' | System | 22 Sep 2020 20:05:30 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:05:30 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:25:00 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 07:51:44 |
| Query 'Data is required. Please complete.' answered with 'Updated' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:06:00 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty; reason for change Data Entry Error | System | 22 Sep 2020 20:05:30 |
| User entered 'Medical History (MH)' | Heather Jimenez (b) (4) | 22 Sep 2020 20:05:30 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:25:00 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:25:00 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data no required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:06 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:06:25 |
| User entered empty. | (b) (4) | |
| | System | 10 Aug 2020 14:25:52 |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:25:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:04 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:06:44 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:06:28 |
| User entered 'Hypertension' | System | 22 Sep 2020 20:06:28 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:06:28 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:25:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:01 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:06:42 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:06:28 |
| User entered 'Medical History (MH)' | System | 22 Sep 2020 20:06:28 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:06:28 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:25:52 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (D) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:25:52 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 07:53:33 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 20:07:10 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Aug 2020 14:28:12 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:28:12 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:31 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:07:23 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:07:13 |
| User entered 'Hypercholesterolemia' | System | 22 Sep 2020 20:07:13 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:07:13 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:28:12 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:29 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:07:29 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:07:13 |
| User entered 'Medical History (MH)' | System | 22 Sep 2020 20:07:13 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:07:13 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:28:12 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (D) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:28:12 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:55 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:04 |
| User entered empty. | (b) (4) | |
| | System | 10 Aug 2020 14:28:44 |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:28:44 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:50 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:14 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:07:55 |
| User entered 'Gastroesophageal' | System | 22 Sep 2020 20:07:55 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:07:55 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:28:44 |
| | (b) (4) | |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:53:53 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:21 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:07:55 |
| User entered 'Medical History (MH)' | System | 22 Sep 2020 20:07:55 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:07:55 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:28:44 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:28:44 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | |
| Signature has been broken. | | |
| User signature succeeded. | Valentine Ebuh (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:54:18 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:37 |
| User entered empty. | (b) (4) | 10 Aug 2020 14:29:12 |
| | System | |
| | Robert Miranda (b) (4) | |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data no required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:54:21 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:48 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:08:40 |
| User entered 'Neuropathy' | System | 22 Sep 2020 20:08:40 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:40 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:29:12 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:54:24 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:55 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:08:40 |
| User entered 'Medical History (MH)' | System | 22 Sep 2020 20:08:40 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:08:40 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:29:12 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:29:12 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 24 Sep 2020 07:13:17 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 20:09:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Aug 2020 14:30:03 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:30:03 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 24 Sep 2020 07:13:20 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:09:28 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:09:21 |
| User entered 'Left Knee Arthroplasty' | System | 22 Sep 2020 20:09:21 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:09:21 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:30:03 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 24 Sep 2020 07:13:22 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:09:36 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty; reason for change Data Entry Error | System | 22 Sep 2020 20:09:21 |
| User entered 'Medical History (MH)' | Heather Jimenez (b) (4) | 22 Sep 2020 20:09:21 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:30:03 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:30:03 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data no required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:55:21 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | 22 Sep 2020 20:10:10 |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:04:23 |
| User closed query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System). | (b) (4) | 22 Sep 2020 20:04:23 |
| User entered empty; reason for change Data Entry Error | System | 22 Sep 2020 20:04:23 |
| User opened query 'Procedure Date is prior to ICF Date. Please verify and reconcile.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:03:46 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | 22 Sep 2020 20:03:46 |
| User entered '01 Jan 2011' reason for change: Data Entry Error | System | 22 Sep 2020 20:03:46 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:03:35 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 22 Sep 2020 20:03:35 |
| User entered 'UN Jan 2011' (non-conformant). | System | 22 Sep 2020 20:03:35 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:03:03 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 22 Sep 2020 20:03:03 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 22 Sep 2020 20:03:03 |
| User entered 'UN 2011' (non-conformant). | Heather Jimenez (b) (4) | 22 Sep 2020 20:03:03 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Aug 2020 14:30:37 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:30:37 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | |
| Signature has been broken. | | |
| User signature succeeded. | Valentine Ebuh (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:55:23 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:10:03 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:04:23 |
| User entered 'Arthritis' | System | |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:04:23 |
| | (b) (4) | 10 Aug 2020 14:30:37 |
| | Robert Miranda (b) (4) | |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 07:55:25 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:10:00 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty; reason for change Data Entry Error | System | 22 Sep 2020 20:04:23 |
| User entered 'Medical History (MH)' | Heather Jimenez (b) (4) | 22 Sep 2020 20:04:23 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:30:37 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:30:37 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 07:56:10 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | Heather Jimenez (b) (4) (b) (4) | 22 Sep 2020 20:10:32 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Aug 2020 14:31:03 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:31:03 |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:56:13 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:10:41 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:10:34 |
| User entered 'COPD' | System | 22 Sep 2020 20:10:34 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:10:34 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:31:03 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:56:15 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:10:50 |
| User entered empty; reason for change Data Entry Error | (b) (4) | 22 Sep 2020 20:10:34 |
| User entered 'Medical History (MH)' | System | 22 Sep 2020 20:10:34 |
| | Heather Jimenez (b) (4) | 22 Sep 2020 20:10:34 |
| | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:31:03 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) | |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:31:03 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:00

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:56:54 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:11:13 |
| User entered empty. | (b) (4) | |
| | System | 10 Aug 2020 14:31:15 |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:31:15 |
| | (b) (4) | |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:00

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:56:56 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:11:21 |
| User entered empty. | (b) (4) | |
| | System | 10 Aug 2020 14:31:15 |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:31:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:00

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 07:56:58 |
| Query 'Data is required. Please complete.' answered with 'Entered in Error' (Site from System). | (b) (4), (b) (6) | |
| User opened query 'Data is required. Please complete.' (Site from System). | Heather Jimenez (b) (4) | 22 Sep 2020 20:11:28 |
| User entered empty. | (b) (4) | |
| | System | 10 Aug 2020 14:31:15 |
| | Robert Miranda (b) (4) | 10 Aug 2020 14:31:15 |
| | (b) (4) | |

US3092021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 15:03:00

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 29 Apr 2021 02:21:53 |
| DataPoint activated with code reason code Data required. | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 16:15:23 |
| DataPoint inactivated with code reason code Data not required. | | 14 Apr 2021 16:14:30 |
| Signature has been broken. | | 14 Apr 2021 16:14:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:31:15 |

US3092021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:00

Date of study discontinuation/completion (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:38:25 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 26 Oct 2020 14:18:38 |
| Query 'Data is required. Please complete.' answered with 'Error, remains in study' (Site from System). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:34:26 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Aug 2020 14:35:31 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:35:31 |

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:00

[Reason for discontinuation](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:38:25 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) (b) (4), (b) (6) | 26 Oct 2020 14:18:41 |
| Query 'Data is required. Please complete.' answered with 'Error, remains in study' (Site from System). | Catina Adams (b) (4) (b) (4) | 23 Oct 2020 16:34:39 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 10 Aug 2020 14:35:31 |
| User entered empty. | Robert Miranda (b) (4) (b) (4) | 10 Aug 2020 14:35:31 |

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:38:25 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:35:31 |

US3092021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:00

[If reason for discontinuation is Death, main cause of death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:38:25 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:35:31 |

US3092021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:00

[If main cause of death is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:38:25 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:35:31 |

US3092021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:00

Date of death (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:38:25 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | (b) (4) Robert Miranda (b) (4) | 10 Aug 2020 14:35:31 |

US3092021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:03:00

[Was autopsy performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 06:38:25 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered empty. | Robert Miranda (b) (4) | 10 Aug 2020 14:35:31 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'USA-US086-2021-MRNA-1273-P301000002' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Valentine' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Ebuh' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered '2701 S Hampton Road, Suite 250' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Dallas' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'TX' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| | (b) (4) | |
| Signature has been broken. | System | 11 Mar 2021 15:09:43 |
| User entered '75033' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '75224' reason for change: Data Entry Error | Robert Miranda (b) (4) | 09 Feb 2021 17:22:36 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 05 Feb 2021 17:39:17 |
| User entered (b) (6) | System | 05 Feb 2021 17:39:17 |
| (non-conformant). | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| | | |
| Un-reviewed for Safety. | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| | | |
| User entered (b) (6) | System | 07 Jan 2021 17:31:22 |
| (non-conformant). | | |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| User entered 'US' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '3' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '2' | System | 05 Feb 2021 17:39:17 |
| User entered '1' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'USA-US086-2021-MRNA-1273-P301000002' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Valentine' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Ebuh' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered '2701 S Hampton Road, Suite 250' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Dallas' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'TX' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| | (b) (4) | |
| Signature has been broken. | System | 11 Mar 2021 15:09:43 |
| User entered '75033' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '75224' reason for change: Data Entry Error | Robert Miranda (b) (4) | 09 Feb 2021 17:22:36 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 05 Feb 2021 17:39:17 |
| User entered (b) (6) | System | 05 Feb 2021 17:39:17 |
| (non-conformant). | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| | | |
| Un-reviewed for Safety. | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| | | |
| User entered (b) (6) | System | 07 Jan 2021 17:31:22 |
| (non-conformant). | | |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| User entered 'US' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '3' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '2' | System | 05 Feb 2021 17:39:17 |
| User entered '1' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:00

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '07/Jan/2021 12:32' | (b) (4) System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:03:00

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. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| User entered 'I' | | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'USA-US086-2021-MRNA-1273-P301000002' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Valentine' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Ebuh' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered '2701 S Hampton Road, Suite 250' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Dallas' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'TX' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| | (b) (4) | |
| Signature has been broken. | System | 11 Mar 2021 15:09:43 |
| User entered '75033' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '75224' reason for change: Data Entry Error | Robert Miranda (b) (4) | 09 Feb 2021 17:22:36 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 05 Feb 2021 17:39:17 |
| User entered (b) (6) | System | 05 Feb 2021 17:39:17 |
| (non-conformant). | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| | | |
| Un-reviewed for Safety. | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| | | |
| User entered (b) (6) | System | 07 Jan 2021 17:31:22 |
| (non-conformant). | | |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| User entered 'US' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '3' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '2' | System | 05 Feb 2021 17:39:17 |
| User entered '1' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:00

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered '05/Feb/2021 17:39' | (b) (4) System | 05 Feb 2021 17:39:17 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:03:00

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. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:39:17 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'USA-US086-2021-MRNA-1273-P301000002' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Yes (Y)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'No (N)' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Valentine' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Ebuh' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered '2701 S Hampton Road, Suite 250' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'Dallas' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| User entered 'TX' | System | 07 Jan 2021 17:31:22 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

Site Address: Postal Code

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| | (b) (4) | |
| Signature has been broken. | System | 11 Mar 2021 15:09:43 |
| User entered '75033' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '75224' reason for change: Data Entry Error | Robert Miranda (b) (4) | 09 Feb 2021 17:22:36 |
| | (b) (4) | |
| Un-reviewed for Safety. | System | 05 Feb 2021 17:39:17 |
| User entered (b) (6) | System | 05 Feb 2021 17:39:17 |
| (non-conformant). | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| | | |
| Un-reviewed for Safety. | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 22 Jan 2021 22:59:48 |
| | (b) (4) | |
| Reviewed for Safety. | (b) (4), (b) (6) | 07 Jan 2021 17:31:52 |
| | | |
| User entered (b) (6) | System | 07 Jan 2021 17:31:22 |
| (non-conformant). | | |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 17:39:09 |
| User entered 'US' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:03:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| User entered '3' | System | 11 Mar 2021 15:09:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 19 Feb 2021 00:23:27 |
| | (b) (4) | |
| User entered '2' | System | 05 Feb 2021 17:39:17 |
| User entered '1' | System | 07 Jan 2021 17:32:02 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:00

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered '11/Mar/2021 07:09' | (b) (4) System | 11 Mar 2021 15:09:43 |

US3092021

Folder: SAE USA-US086-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:03:00

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. | Valentine Ebuh (b) (4) | 23 Mar 2021 22:38:13 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 11 Mar 2021 15:09:43 |